WYETH

3699463-9-00-01

MEDWATCH

AL PRODUCTS REPORTING PROGRAM

Approved by the FDA on 09/24/1999

Mfr report # HQ6622130MAY2000

uF/Dist report #

FDA Use Only

A. Patient information

1. Patient identifier [redacted] n confidence

2. Age at time of event: or 67Yr

Date of Birth: [redacted]

3. Sex: [ ] female [X] male

4. Weight: 215 lbs or kgs

B. Adverse event or product problem

1. [X] Adverse event [ ] Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

[ ] death (mo/day/yr)
[ ] life-threatening
[X] hospitalization-initial or prolonged
[X] recovered
[ ] disability
[ ] congenital anomaly
[ ] required intervention to prevent permanent impairment/damage
[ ] other:

3. Date of event (mo/day/yr): 00/00/1999

4. Date of this report (mo/day/yr): 03/28/2001

5. Describe event or problem

Information was received on 26-MAY-2000 from a physician via Merck & Co., Inc. and on 12-JUN-2000 from a registered nurse via Covance regarding a 67-year-old white male patient. The patient's concurrent illnesses include Arthritis NOS. Additional medical history was not provided. Therapy with LODINE CAPSULE (etodolac capsule) for Arthritis NOS began in 1999 (therapy dates not specified). The dose regimen included: two, 500mg doses, every day. Additional suspect medication included ACETYLSALICYLIC ACID and NAPROXEN SODIUM. The patient experienced stomach bleeding (Gastrointestinal haemorrhage NOS) while taking LODINE CAPSULE and ACETYLSALICYLIC ACID (Drug interaction NOS). He was subsequently hospitalized for two days and nights. The patient "was fine" at the time of discharge and continued LODINE CAPSULE therapy (ACETYLSALICYLIC ACID was discontinued). In follow-up information received on 12-JUN-2000, the nurse indicated the patient was taking LODINE CAPSULE (etodolac capsule) concomitantly with

(cont'd)

6. Relevant tests/laboratory data, including dates

None Provided.

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction etc.)

CONCURRENT CONDITIONS:
Arthritis NOS

C. Suspect medication(s)

1. Name (give labeled strength & manufacturer, if known)

#1 LODINE (ETODOLAC, Capsule)

#2 ACETYLSALICYLIC ACID (ACETYLSALICYLIC ACID,) (cont'd)

2. Dose, frequency & route used

#1 500 mg 2x per 1 Day, Oral

#2 Dose not specified, Oral

3. Therapy dates (if unknown, give duration)

#1 00/00/1999 to UNK

#2 00/00/1999 to UNK

4. Diagnosis for use (indication)

#1 Arthritis NOS

#2 UNK

5. Event abated after use stopped or dose reduced

#1 [ ] yes [ ] no [X] doesn't apply

#2 [ ] yes [ ] no [X] doesn't apply

6. Lot # (if known)

#1

#2

7. Exp date (if known)

#1

#2

8. Event reappeared after reintroduction

#1 [ ] yes [X] no [ ] doesn't apply

#2 [ ] yes [ ] no [X] doesn't apply

9. NDC # – for product problems only (if known)

10. Concomitant medical products and therapy dates (exclude treatment of event)

UNK

G. All manufacturers

1. Contact office – name/address

WYETH LABS (RA)
240 N Radnor-Chester
St. Davids, PA 19087

Jill Robinson

2. Phone number: 6109024647

3. Report source (check all that apply)

[ ] foreign
[ ] study
[ ] literature
[ ] consumer
[X] health professional
[ ] user facility
[ ] company representative
[ ] distributor
[ ] other:

4. Date received by manufacturer (mo/day/yr): 05/26/2000

5. (A)NDA 18-922
IND #
PLA #
pre-1938 [ ] yes
OTC product [ ] yes

6. If IND, protocol #

7. Type of report

[ ] 5-day [ ] 15-day
[ ] 10-day [X] periodic
[X] initial [ ] follow-up #

8. Adverse event term(s)

Gastrointestinal haemorrhage NOS
Drug interaction NOS

9. Mfr. report number

HQ6622130MAY2000

E. Initial reporter

1. Name & address

Hostelley, Linda S., Dr.
Merck & Co., Inc.
PO Box 4
West Point, PA 19486, US

phone # 610-397-2416

2. Health professional? [X] yes [ ] no

3. Occupation: Physician

4. Initial reporter also sent report to FDA: [ ] yes [ ] no [X] unk

FDA Form 3500A (facsimile)

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

WYETH

MEDWATCH

PRODUCTS REPORTING PROGRAM

Approved by the FDA on 09/24/1999

Mfr report # HQ6622130MAY2000

UF/D st report a

FDA Use Only

3699463-9-00-02

Box B.5 - Describe event or problem (Continuation)

Aleve (NAPROXEN SODIUM). Additional information has been requested.

Box C - Suspect medication(s) (Continuation)

1. Name (give labeled strength & mfr/labeler, if known)

3.1 NAPROXEN SODIUM (NAPROXEN SODIUM,)

2. Dose, frequency & route used

3.1 1 Tablet 2x per 1 Day, Oral

3. Therapy dates (if unknown, give duration)

3.1 05/31/1999 to 05/31/1999

4. Diagnosis for use (indication)

3.1 Arthritis NOS

5. Event abated after use stopped or dose reduced

3.1 DOESN'T APPLY

6. Lot # (if known)

3.1

7. Exp date (if known)

8 Event reappeared after reintroduction

3.1 DOESN'T APPLY

Merck Human Health Division

Individual Safety Report

3703119-3-00-01

...ir use by user-facilities,
...tors and manufacturers for
MANDATORY reporting

Page 1 of 1

Merck Facsimile of FDA Form 3500A
Approved by FDA (10/21/93)

Mfr report # WAES C1022014

UF/Dist report #

FDA Use Only

A. Patient information

1. Patient identifier	2. Age at time of event:	3. Sex	4. Weight
[redacted]	or 77 years	☐ Female	205 pounds
n confidence	Date of Birth: [redacted]	☒ Male	

B. Adverse event or product problem

1: ☒ Adverse event and / or ☐ Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

- ☐ death ____ (mo/day/yr)
- ☒ life-threatening
- ☒ hospitalization-initial or prolonged
- ☒ disability
- ☐ congenital anomaly
- ☐ required intervention to prevent permanent impairment/damage
- ☒ other: important medical

3. Date of event (mo/day/yr): 01/31/01

4. Date of this report (mo/day/yr): 04/04/01

5. Describe event or problem

This is in follow-up to report(s) previously submitted on 3/1/01; 3/7/01

Information has been received from a physician, medical records, and a completed questionairre concerning a 77 year old white male with hypertension (approximately 1991), type 2 diabetes mellitus, hypertensive coronary vascular disease, epigastric pain, smoking (approximately one pack a day), occasional alcohol consumption, hypercholesterolemia, a penicillin allergy, chronic anti-coagulation (1991), spinal stenosis, intervertebral disc disorder, depression (1972), congestive heart failure with orthopnea and shortness of breath on exertion, and a history of a "recent" upper respiratory infection, peptic ulcer disease (1972) "off and on", "active" ulcer (1978), headache, dizziness, coronary artery stent placement (1991,1996), adenoidectomy, tonsillectomy (1943), angioplasty (1991, twice in 1996), low back pain (1983), appendectomy (1937), acute inferior myocardial infarction (1987, 1996), myocardial infarction (1993), ankle sprain (December 2000), cardiac

(Continued on Additional Page)

6. Relevant tests/laboratory data, including dates

Refer to Additional Page

CENTER FOR DRUG EVALUATION AND RESEARCH RECD APR 11 2001 DDR

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc)

MEDICAL HISTORY: acute anterior myocardial infarction; acute inferior myocardial infarction; adenoidectomy; angioplasty; appendectomy; arterial thrombosis, cardiac catheterization; chest pain; coronary artery stent placement; upper respiratory infection; transurethra, prostatectomy; tonsillectomy; pseudoaneurysm.

(Continued on Additional Page)

FDA Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)

#1 TAB VIOXX Unk

#2

(Continued on Additional Page)

2. Dose, frequency & route used	3. Therapy dates (from/to or duration)
#1 50 mg/DAILY/PO	#1 11/27/00 - 11/29/00
#2	#2

4. Diagnosis for use (indication)

#1 pain, osteoarthritis

#2

5. Event abated after use stopped or dose reduced

	yes	no	N/A	unk
#1	☒	☐	☐	☐
#2	☐	☐	☐	☐

6. Lot # (if known)

#1

#2

7. Exp date (if known)

#1

#2

8. Event reappeared after reintroduction

	yes	no	N/A	unk
#1	☐	☐	☒	☐
#2	☐	☐	☐	☐

9. NDC # - for product problems only (if known)

Unknown

10. Concomitant medical products and therapy dates (exclude treatment of event)

ACTOS Unk -Unk

DARVOCET-N Unk -Unk

(Continued on Additional Page)

G. All manufacturers

1. Contact office - name/address

Merck Human Health Division
Merck & Co., Inc.
P.O. Box 4
West Point, PA 19486-0004

ATTN: Worldwide Product Safety

2. Phone Number: (610)397-2416

3. Report source (check all that apply)

- ☐ foreign
- ☐ study
- ☐ literature
- ☐ consumer
- ☒ health professional
- ☐ user facility
- ☒ company representative
- ☐ distributor
- ☐ other

4. Date received by manufacturer (mo/day/yr): 03/28/01

5. (A)NDA # 21042

IND #

PLA #

pre-1938 ☐ yes

OTC product ☐ yes

6. If IND, protocol #

7. Type of report

- ☐ 5-day
- ☒ 15-day
- ☐ 10-day
- ☐ periodic
- ☐ initial
- ☒ Follow-up# 2

9. Mfr. report number: WAES 01022014

8. Adverse event term(s)

HEMORRHAGIC DUODENAL ULCER; GASTRITIS

APR 11 2001

E. Initial reporter

1. Name, address & phone #

[redacted]

2. Health professional?	3. Occupation	4. Initial reporter also sent report to FDA
☒ YES ☐ NO	M.D.	☐ yes ☐ no ☒ unk

B. Adverse event or product problem

5. Describe event or problem

catheterization (1991, 1996), right femoral arterial thrombosis (1991), pseudoaneurysm (1991), transurethral prostatectomy (1985), nephrolithiasis (1967, 1983), pertussis (age 9), chest pain (1972), and acute anterior myocardial infarction (1991). The patient's family history included: father with "heart trouble" who died in his late 70's after a colon resection for diverticulitis, mother who had a pacemaker and who died at age 70 of diabetes and high blood pressure, grandfather who died at age 65 with kidney disease, and grandmother who died of diabetes. On 27-NOV-2000 the patient was placed on therapy with rofecoxib, tablet, 50 mg daily for three days, then 25 mg, once daily, for the treatment of back pain sometimes radiating to the legs and osteoarthritis. Concomitant therapy included warfarin sodium (COUMADIN), 7.5 mg daily except for Tuesdays, as anti-coagulant therapy and "baby" aspirin, 81 mg, one daily, as cardiovascular disorder prophylaxis. Other concomitant therapy included amlodipine besylate (NORVASC), metformin HCl (GLUCOPHAGE), pioglitazone hydrochloride (ACTOS), ferrous sulfate (SLOW FE), pravastatin Na (PRAVACHOL), acetaminophen (+) propoxyphene napsylate (DARVOCET-N) and furosemide (LASIX). Prior therapy included ranitidine hydrochloride (Zantac) for treatment of peptic ulcer disease. In January 2001 the patient developed flu-like symptoms with mild nausea, headaches, myalgias, and anorexia. On 31-JAN-2001 the patient felt better and ate a breakfast consisting of pancakes and sausage. At approximately 1:00 pm on 31-JAN-2001 the patient had an episode of massive emesis which he'd attributed to bad sausage. Two hours later the patient had a second episode of emesis. That day, the patient went to the emergency room. Current medications on admission included amlodipine besylate, warfarin sodium, metformin HCl, pravastatin Na, aspirin, and acetaminophen + propoxyphene napsylate. The patient complained that he had some lightheadedness, worsening orthopnea and shortness of breath on exertion, and a mild nonproductive cough. There was no chest pain or palpitations. The patient noted his history of ongoing epigastric pain on and off, and reported that on that day it was located to the epigastrium and was non radiating, not associated with emesis. The patient denied hematemesis, hematochezia, melena, urinary hesitancy, urinary urgency, urinary burning or dysuria. Upon physical examination blood pressure was 148/59, pulse was 111, respirations were 16, temperature was 98.9 F, and pulse oximetry 94% on room air. Neck demonstrated positive jugular venous distention. Lungs showed bibasilar crackles. Heart showed mild tachycardia without murmur, and peripheral pulses were 2+. Abdomen was soft with bowel sounds in all four quadrants. There was mild epigastric tenderness with mild guarding, no rebound. Mild left lower quadrant tenderness without guarding or rebound, and no masses were noted. Rectal exam demonstrated good tone, prostate was not inflamed, stool was fecal occult blood positive. On 31-JAN-2001 a chest x-ray revealed mild congestive heart failure with fluid in the costophrenic gutter, as well as mild cardiomegaly with cephalization. Laboratory test results on 31-JAN-2001 revealed a white blood cell count (WBC) of 12.7, hemoglobin of 13 ("initial" hemoglobin also reported as 12.3), hematocrit of 38.5, platelet count of 395000, mild monocytosis of 6.6%, prothrombin time (PT) of 22.3 sec, International Normalized Ratio (INR) of 3.8, sodium of 145, potassium of 4.6, chloride of 111, bicarbonate of 25, glucose of 220, blood urea nitrogen (BUN) of 48, creatinine of 1.3, calcium of 9.1, alanine aminotransferase (ALT) of 39, aspartate aminotransferase (AST) of 17, creatine kinase (CK) of 47, CK-MB of 0.9, alkaline phosphatase of 73, total bilirubin of 0.3, cholesterol of 127, amylase of 31, and troponin I of <0.35. A flat and upright KUB demonstrated normal bowel gas pattern, no free air and no masses seen. The patient was admitted with an initial impression of gastrointestinal bleeding with congestive heart failure, and was treated with a moderate sliding scale and H2 antagonist. On 31-JAN-2001 rofecoxib was discontinued. Early in the morning on 01-FEB-2001 the patient developed frank gastrointestinal bleeding with melena and burgundy-colored stools, vomited blood, and was transferred to the critical care unit for further treatment. On 01-FEB-2001 the patient's primary care physician was consulted. Upon physical examination the patient appeared "acutely and chronically ill" with blood pressure of 100/70, pulse of 110 and respirations at 18. It was noted to be difficult to obtain any kind of detailed information from the patient, and he was noted to have a catheter in place which he complained severely of. The patient was rather pale, conjunctivae were very pale, there was no edema. Heart had no murmur, snocks, thrills, gallops, or friction rub. Abdominal examination showed a lot of epigastric tenderness. There was no real rebound or rigidity; however, examination was noted to be difficult to perform due to the extent of the patient's discomfort. Additional laboratory test results were reported to reveal a hematocrit of 37, hemoglobin 9.3, and subsequent hematocrit of 28. Stools were noted to be black and tarry. The primary care physician's initial impression was possible bleeding from a Mallory-Weiss tear secondary to the repeated vomiting or from a duodenal ulcer, possible gallbladder disease or pancreatitis, concern for maintaining hemoglobin and hematocrit above 10 due to the patient's pre-existing coronary artery disease, hypertensive cardiovascular disease under treatment, hypercholesterolemia, persistent low back pain sometimes radiating to the left leg occasionally to the right leg and occasionally no pain. The patient was treated with vitamin K and transfusion with three units of fresh frozen plasma was ordered "to try to reverse the pro-time", long term anticoagulant therapies for history of repeated myocardial infarctions were reversed, gastrointestinal consult was ordered, amylase was to be checked, and a myelogram was recommended. Following transfusion on 01-FEB-2001, gastrointestinal consult examination was performed during which the patient reported feeling better with no chest pain or shortness of breath and somewhat improved abdominal pain. The patient denied fever or chills, loss of weight, headaches, sore throat, dysphagia or odynophagia, dysuria or hematuria. There was no chest pain, palpitations, coughing or wheezing, but the patient did note occasional shortness of breath. Upon physical examination the patient was in no acute distress, was afebrile with a heart rate of 86 and blood pressure of 112/61. Conjunctivae were somewhat pale and mucous membranes were dry. Carotid pulses were 2+, there were no bruits or lymphadenopathy. Lungs revealed scattered wheezes with no crackles. Heart rate and rhythm were regular without murmurs, rubs or gallops. Abdomen was soft with mild epigastric tenderness to palpitation. There was no rebound, guarding or masses. Bowel sounds were normoactive and rectal examination showed no frank melena. Hemoglobin was noted to have been 13 at admission, with a subsequent drop to 11, then to 9, and at the time of examination it was 7.2. Initial INR was noted to be 3.8 and, following fresh frozen plasma and vitamin K, it was 2.2. Additional laboratory test results on 01-FEB-2001 lipase was 117, amylase was "normal" (value not specified), sodium was 145, potassium was 4.3, chloride was 111, bicarbonate was 24, glucose was 207, BUN was 81, creatinine was 1.6, calcium was 8.6, ALT was 39, AST was 17, troponin I was

0.035, alkaline phosphatase was 75, bilirubin was 0.3, and albumin was 2.8. Chest x-ray was "normal." The gastrointestinal consult physician suspected that the patient had "an upper gastrointestinal bleed, probably due to a peptic ulcer given his history, as well as non-steroidal anti-inflammatory drug use and [Coumadin]." Additional transfusion was ordered with two units of fresh frozen plasma and packed red blood cells, until hemoglobin was 10. The patient was also to be monitored for worsening congestive heart failure, and upper endoscopy was planned for when INR was less than 1.5. Subsequently, the patient was treated with furosemide, empiric famotidine (MSD). On 02-FEB-2001 laboratory test results revealed that sodium was 151, potassium was 4.1, chloride was 120, bicarbonate was 29, glucose was 146, BUN was 67, serum creatinine was 1.3, calcium was 8.2, PT was 13.6 sec, PT normal count was 11.3 sec, and INR was 1.4. On 02-FEB-2001 an esophagogastroduodenoscopy was performed. The esophagus and duodenum were normal. In the duodenal bulb there was a 1 cm ulcer. There were two flat spots as well as some erythema and minimal oozing from the periphery. The area was washed and the spots did not appear to be raised at all. A small amount of cautery was placed on the periphery of the ulcer and the area was injected with a total of 2 cc of epinephrine in 1:10,000 dilution. Following those maneuvers there was no bleeding from the ulcer, and the ulcer was thought to be at a relatively low risk for re-bleed. As the scope was brought back in the gastric antrum there was some congested mucosa and a biopsy was taken for Helicobacter pylori. Retroflexion maneuver was performed which showed the stomach to have the appearance of mild gastropathy. Gastritis status post biopsy was noted. The scope was removed. The patient tolerated the procedure well, and there were no immediate complications. The patient was started on lansoprazole (Prevacid), 30 mg daily and a clear liquid diet was initiated. The patient was instructed not to resume aspirin or warfarin sodium until further notice. Findings from the gastric antrum biopsy evaluation revealed mild to moderate chronic inflammation of the gastric mucosa with plasma cells expanding the superficial lamina propria. Some lymphocytes and scattered eosinophils were also seen. There was no significant activity noted and no atypical or malignant features were identified. Modified Writght's stain showed small numbers of Helicobacter Pylori organisms. On 04-FEB-2001 laboratory test results revealed that sodium was 147, potassium was 4.4, chloride was 114, bicarbonate was 30, glucose was 138, BUN was 20, creatinine was 1.1, and calcium was 8.3. On 05-FEB-2001 hemoglobin was 10.8 g/dL and hematocrit was 31.9%. On 09-MAR-2001 the patient was started on therapy with ramipril (Altace). At the time of this report the patient had recovered from the bleeding duodenal ulcer, but continued to receive treatment with lansoprazole, clarithromycin (Biaxin) and metronidazole (Flagyl).

The elevated BUN, elevated serum creatinine, cardiomegaly, tachycardia, worsening congestive heart failure, mild monocytosis, and cough were considered to be incidental findings. The bleeding duodenal ulcer was considered to be immediately life-threatening, disabling, and an Other Important Medical Event. Additional information is not expected.

6. Relevant tests/laboratory data, including dates

DIAGNOSTIC TEST

Tests	Date	Value	Unit	Normal Range
blood pressure measurement Comment: 148/59	01/31/01			
chest X-ray Comment: mild CHF with fluid in the costophrenic gutter as well as mild cardiomegaly w/cephalization	01/31/01			
pulse oximetry Comment: on room air	01/31/01	94	%	
blood pressure measurement Comment: 112/61	02/01/01			
blood pressure measurement Comment: 100/70	02/01/01			
chest X-ray Comment: normal	02/01/01			
esophagogastroduodenoscopy Comment: duodenal ulcer in the bulb as well as oozing in the periphery, gastritis s/p biopsy	02/02/01			
gastric biopsy Comment: chronic gastritis with small numbers of Helicobacter Pylori organisms	02/02/01			

LABORATORY RESULTS

Tests	Date	Value	Unit	Normal Range
INR	01/31/01	3.8		
WBC count	01/31/01	13.7		
blood glucose	01/31/01	220		
body temp	01/31/01	98.8	F	
hematocrit	01/31/01	38.5		
hemoglobin	01/31/01	13.0		
hemoglobin	01/31/01	12.3		
hemoglobin	01/31/01	9.0		
hemoglobin	01/31/01	11.0		
hemoglobin	01/31/01	6.6	%	
monocyte count	01/31/01	395000		
platelet count	01/31/01	<0.35		
serum TnI	01/31/01	39		
serum alanine aminotransferase				

serum alkaline phosphatase	01/31/01	73		
serum aspartate aminotransferase	01/31/01	17		
serum bicarbonate	01/31/01	25		
serum blood urea nitrogen	01/31/01	48		
serum calcium	01/31/01	9.1		
serum chloride	01/31/01	111		
serum cholesterol	01/31/01	127		
serum creatine kinase	01/31/01	47		
serum creatine kinase isoenzyme MB	01/31/01	0.9		
serum creatinine	01/31/01	1.3		
serum potassium	01/31/01	4.6		
serum sodium	01/31/01	145	mmol/L	140 - 148
stool occult blood	01/31/01			
Comment: positive				
total serum bilirubin	01/31/01	0.3		
vital sign	01/31/01			
Comment: pulse 111, respiration 16				
prothrombin time	01/31/01	23.3	sec	
serum amylase test	01/31/01	31		
INR	02/01/01	2.2		
blood glucose	02/01/01	207	mg/dL	70 - 110
hematocrit	02/01?/01	37		
hematocrit	02/01?/01	28		
hemoglobin	02/01/01	7.2		
hemoglobin	02/01?/01	9.3		
serum TnI	02/01/01	0.035		
serum alanine aminotransferase	02/01/01	39		
serum albumin	02/01/01	2.8		
serum alkaline phosphatase	02/01/01	75		
serum aspartate aminotransferase	02/01/01	17		
serum bicarbonate	02/01/01	24	mmol/L	21 - 32
serum blood urea nitrogen	02/01/01	81	mg/dL	6 - 20
serum calcium	02/01/01	8.6	mg/dL	8.7 - 10.5
serum chloride	02/01/01	111	mmol/L	100 - 108
serum creatinine	02/01/01	1.6	mg/dL	0.6 - 1.0
serum potassium	02/01/01	4.3	mmol/l	3.6 - 5.2
serum sodium	02/01/01	145	mmol/L	140 - 148
total serum bilirubin	02/01/01	0.3		
vital sign	02/01/01			
Comment: heart rate 86				
vital sign	02/01/01			
Comment: pulse 110, respirations 18				
serum amylase test	02/01/01			
Comment: normal				
serum lipase test	02/01/01	117		
INR	02/02/01	1.4		2.0 - 3.0
blood glucose	02/02/01	146	mg/dL	70 - 110
serum bicarbonate	02/02/01	29	mmol/L	21 - 32
serum blood urea nitrogen	02/02/01	67	mg/dL	6 - 20
serum calcium	02/02/01	8.2	mg/dL	8.7 - 10.5
serum chloride	02/02/01	120	mmol/L	100 - 108
serum creatinine	02/02/01	1.3	mg/dL	0.6 - 1.0
serum potassium	02/02/01	4.1	mmol/L	3.6 - 5.2
serum sodium	02/02/01	151	mmol/L	140 - 148
prothrombin time	02/02/01	13.6	sec	10.9 - 13.1
prothrombin time	02/02/01	11.3	sec	
Comment: "PT normal count"				
blood glucose	02/04/01	138	mg/dL	70 - 110
serum bicarbonate	02/04/01	30	mmol/L	21 - 32
serum blood urea nitrogen	02/04/01	20	mg/dL	6 - 20
serum calcium	02/04/01	8.3	mg/dL	8.7 - 10.5
serum chloride	02/04/01	114	mmol/L	100 - 108
serum creatinine	02/04/01	1.1	mg/dL	0.6 - 1.0
serum potassium	02/04/01	4.4	mmol/L	3.6 - 5.2
serum sodium	02/04/01	147	mmol/L	140 - 148
hematocrit	02/05/01	31.9	%	42 - 52
hemoglobin	02/05/01	10.9	g/dL	14.0 - 18.0

7. Other relevant history including preexisting medical conditions

pertussis; peptic ulcer; nephrolithiasis; myocardial infarction; low back pain; headache; dizziness; ankle sprain
CONCURRENT CONDITIONS: Helicobacter infection; cardiomegaly; congestive heart failure; epigastric pain; hypertension; type 2 diabetes mellitus; tachycardia; spinal stenosis; smoking; serum creatinine increased; penicillin allergy; orthopnea; monocytes increased; intervertebral disc disorder; hypertensive heart disease; hypercholesterolemia; exertional dyspnea; depression; cough; coronary artery disease; blood urea nitrogen increased; alcohol consumption

C. Suspect medication(s)

1. Name (Given labeled strength & mfr/labeler, if known)

#1 TAB VIOXX 25 mg
#2 COUMADIN Unk
#3 TAB aspirin Unk

2. Dose, frequency & route used

#1 25 mg/DAILY/PO
#2 7.5 mg/DAILY/PO
#3 81 mg/DAILY/PO

3. Therapy dates (from/to) (if unknown, give duration)

#1 11/30/00 - 01/31/01
#2 ??/??/96 - 01/31/01
#3 Unk - 01/31/01

4. Diagnosis for use (indication)

#1 pain, osteoarthritis
#2 coronary artery disease, coronary artery disease prophylaxis
#3 cardiovascular disorder prophylaxis

5. Event abated after use stopped or dose reduced

	YES	NO	N/A	UNK
#1	X			
#2				X
#3				X

6. Lot # (if known)

#1
#2
#3

7. Exp date (if known)

#1
#2
#3

8. Event reappeared after reintroduction

	YES	NO	N/A	UNK
#1			X	
#2				X
#3				X

C. Suspect medication(s)

10. Concomitant medical products and therapy dates (exclude treatment of event)

GLUCOPHAGE	Unk - Unk
LASIX	Unk - Unk
NORVASC	Unk - Unk
PRAVACHOL	Unk - Unk
SLOW FE	Unk - Unk

FDA ATTACHMENT

RUN DATE: 03/21/01
RUN TIME: 0930

[redacted] LAB **LIVE**
Specimen Inquiry
[redacted]

PAGE 1

PATIENT: [redacted]
REG DR: [redacted] M.D.

ACCT #: [redacted]
AGE/SX: 77/M
DOB: [redacted]
STATUS: DIS IN

LOC: [redacted]
ROOM: [redacted]
BED: 01
TLOC:

U #: [redacted]
REG: 01/31/01
DIS: 02/05/01

SPEC #: [redacted]
RECD: 02/02/01-1527
COLL: 02/02/01-1200
STATUS: SOUT
SUBM DR: [redacted] M.D.
REQ #: [redacted]

ENTERED: 02/02/01-1528
ORDERED: STAINGR1, PATHGM4
SP TYPE: SURGICAL
OTHR DR: BAMC

SURGERY INFORMATION:

Surgery date 02/02/01
Surgeon(s): DR [redacted]

CLINICAL HISTORY

GI BLEEDING

[redacted]
3703119-3-00-07

FINAL DIAGNOSIS

BIOPSIES OF GASTRIC ANTRUM: CHRONIC GASTRITIS WITH SMALL NUMBERS OF HELICOBACTER PYLORI ORGANISMS.

GROSS DESCRIPTION

The specimen is submitted in formalin labeled as "gastric antrum." Submitted are two fragments, 1-2 mm, embedded in total in one block.

Dictated by [redacted], M.D.

MICROSCOPIC DESCRIPTION

The sections show fragments of gastric antral type mucosa in which there is mild to moderate chronic inflammation with plasma cells expanding the superficial lamina propria. Some lymphocytes and scattered eosinophils are also seen. No significant activity is present and no atypical or malignant features are identified. The modified Wright's stain shows small numbers of Helicobacter pylori organisms.

Dictated by: [redacted], M.D.
02/03/01 - 1320 EDIX.JLB

JOB
[redacted]

** CONTINUED ON NEXT PAGE **

APR 1 2001

FDA ATTACHMENT

RUN DATE: 03/21/01
RUN TIME: 0930

[redacted] LAB **LIVE**
Specimen Inquiry

SPEC #: [redacted] PATIENT: [redacted] (Continued)

CODES: ANTRUM, NOS

COPIES TO:
BAMC

[redacted] M.D.
[redacted] Suite [redacted]
[redacted]

HISTOLOGY:

TISSUE	ID	BLK	PCS	CAS	LEV	/	PROCEDURE	DISPOSITION
ANTRUM, NOS	A	1						

ICD CODES: 535.50 - UNSP GASTRITIS & GASTRODUODENITIS W/O MENTN HEMORG

PROCEDURES: STAINGR1 (Incomplete)
PATHGM4 (Incomplete)

TISSUES:
A. ANTRUM, NOS - BIOSPY ANTRUM

Signed Signature on file [redacted] M.D. 02/05/01

** END OF REPORT **

APR 11 2001

FDA ATTACHMENT

RUN DATE: 03/21/01
RUN TIME: 0931

[redacted] LAB **LIVE**

Specimen Inquiry

[redacted]

PAGE 1

PATIENT: [redacted]
REG DR: [redacted] M.D.

ACCT #: [redacted]
AGE/SX: 77/M
DOB: [redacted]
STATUS: DIS IN

LOC: [redacted]
ROOM: [redacted]
BED: 01
TLOC:

U #: [redacted]
REG: 01/31/01
DIS: 02/05/01

SPEC #: [redacted]
COLL: 02/01/01-0220
RECD: 02/01/01-0228

STATUS: COMP
SUBM DR: [redacted] M.D.
REQ #: [redacted]

OTHR DR: [redacted] M.D

ENTERED: 02/01/01-0120
ORDERED: BASIC MET
COMMENTS: Campus? COCBA

Test	Result	Flag	Reference	Site
BASIC MET				
> SODIUM	145		140-148 MMOL/L	22
> POTASSIUM	4.3		3.6-5.2 MMOL/L	22
> CHLORIDE	111	H	100-108 MMOL/L	22
> BICARBONATE	24		21-32 MMOL/L	22
> GLUCOSE	207	H	70-110 MG/DL	22
> BUN	81	H	6-20 MG/DL	22
> SERUM CREAT	1.6	H	0.6-1.0 MG/DL	22
> CALCIUM	8.6	L	8.7-10.5 MG/DL	22

22 [redacted] Medical Center, [redacted]
CAP# [redacted] CLIA# [redacted] MEDICARE# [redacted]

Individual Safety Report

3703119-3-00-09

** END OF REPORT **

APR 1 1 2002

[redacted] Waas Num 01022014 [redacted]

FDA ATTACHMENT

RUN DATE: 03/21/01 [redacted] MC LAB **LIVE** PAGE 1
RUN TIME: 0930 Specimen Inquiry
[redacted]

PATIENT: [redacted] ACCT #: [redacted] LOC: [redacted] U #: [redacted]
AGE/SX: 77/M ROOM: [redacted] REG: 01/31/01
REG DR: [redacted] M.D. DOB: [redacted] BED: 01 DIS: 02/05/01
STATUS: DIS IN TLOC:

SPEC #: [redacted] COLL: 02/02/01-0830 STATUS: COMP REQ #: [redacted]
RECD: 02/02/01-0836 SUBM DR: [redacted] M.D.

ENTERED: 02/02/01-0002 OTHR DR: [redacted] M.D.
ORDERED: BASIC MET
COMMENTS: DATE/TIME 02/02/01
/ 0500
Campus? COCBA

	Test	Result	Flag	Reference	Site
	BASIC MET				
>	SODIUM	151	H	140-148 MMOL/L	22
>	POTASSIUM	4.1		3.6-5.2 MMOL/L	22
>	CHLORIDE	120	H	100-108 MMOL/L	22
>	BICARBONATE	29		21-32 MMOL/L	22
>	GLUCOSE	146	H	70-110 MG/DL	22
>	BUN	67	H	6-20 MG/DL	22
>	SERUM CREAT	1.3	H	0.6-1.0 MG/DL	22
>	CALCIUM	8.2	L	8.7-10.5 MG/DL	22

22 - [redacted] Medical Center [redacted]
CAP# [redacted] CLIA# [redacted] MEDICARE# [redacted]

Individual Safety Report
3703119-3-00-10

APR 1 1 2001

** END OF REPORT **

FDA ATTACHMENT

RUN DATE: 03/21/01 [redacted] LAB **LIVE** PAGE 1
RUN TIME: 0930 Specimen Inquiry
[redacted]

PATIENT: [redacted] ACCT #: [redacted] LOC: [redacted] U #: [redacted]
AGE/SX: 77/M ROOM: [redacted] REG: 01/31/01
REG DR: [redacted] M.D. DOB: [redacted] BED: 01 DIS: 02/05/01
STATUS: DIS IN TLOC:

SPEC #: [redacted] COLL: 02/04/01-0444 STATUS: COMP REQ #: [redacted]
RECD: 02/04/01-0531 SUBM DR: [redacted] M.D.

ENTERED: 02/04/01-0003
ORDERED: BASIC MET
COMMENTS: Campus? COCBA
VENOUS SAMPLE
OTHR DR: [redacted] M.D.

	Test	Result	Flag	Reference	Site
	BASIC MET				
>	SODIUM	147		140-148 MMOL/L	22
>	POTASSIUM	4.4		3.6-5.2 MMOL/L	22
>	CHLORIDE	114	H	100-108 MMOL/L	22
>	BICARBONATE	30		21-32 MMOL/L	22
>	GLUCOSE	138	H	70-110 MG/DL	22
>	BUN	20		6-20 MG/DL	22
>	SERUM CREAT	1.1	H	0.6-1.0 MG/DL	22
>	CALCIUM	8.3	L	8.7-10.5 MG/DL	22

22 [redacted] Medical Center [redacted]
CAP# [redacted] CLIA# [redacted] MEDICARE# [redacted]

Individual Safety Report
3703119-3-00-11

** END OF REPORT **

APR 11 2001

[redacted] Waes Num 01022014 [redacted]

Individual Safety Report
3703187-9-00-01

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VOLUNTARY reporting
by health professionals of adverse
events and product problems

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page of

Form Approved: OMB No. 0910-0291 Expires:
See OMB statement on reverse

FDA Use Only

Triage unit sequence # 140963

A. Patient information

1. Patient identifier — In confidence
2. Age at time of event: or Date of birth: [redacted]
3. Sex: [x] female [ ] male
4. Weight: lbs or kgs

B. Adverse event or product problem

1. [x] Adverse event and/or [ ] Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)
- [ ] death (mo/day/yr)
- [ ] life-threatening
- [x] hospitalization – initial or prolonged
- [ ] disability
- [ ] congenital anomaly
- [ ] required intervention to prevent permanent impairment/damage
- [ ] other

3. Date of event (mo/day/yr): 5/22/00
4. Date of this report (mo/day/yr): 3/3/01

5. Describe event or problem

6. Relevant tests/laboratory data, including dates

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

NKDA, ETOH, 1ppd/30years
PMHx: hypertension, hypothyroidism, arthritis
S/P arthroscopy R knee; breast cyst

CTU/140963

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
#1 Celebrex
#2

2. Dose, frequency & route used
#1
#2

3. Therapy dates (if unknown, give duration) from/to (or best estimate)
#1
#2

4. Diagnosis for use (indication)
#1 arthritis
#2

5. Event abated after use stopped or dose reduced
#1 [ ] yes [ ] no [ ] doesn't apply
#2 [ ] yes [ ] no [ ] doesn't apply

6. Lot # (if known)
#1
#2

7. Exp. date (if known)
#1
#2

8. Event reappeared after reintroduction
#1 [ ] yes [ ] no [x] doesn't apply
#2 [ ] yes [ ] no [ ] doesn't apply

9. NDC # (for product problems only)

10. Concomitant medical products and therapy dates (exclude treatment of event)

D. Suspect medical device

1. Brand name
2. Type of device
3. Manufacturer name & address
4. Operator of device
- [ ] health professional
- [ ] lay user/patient
- [ ] other

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5. Expiration date (mo/day/yr)
6. model # / catalog # / serial # / lot # / other #
7. If implanted, give date (mo/day/yr)
8. If explanted, give date (mo/day/yr)
9. Device available for evaluation? (Do not send to FDA) [ ] yes [ ] no [ ] returned to manufacturer on (mo/day/yr)
10. Concomitant medical products and therapy dates (exclude treatment of event)

E. Reporter

1. Name, address

[redacted] HOSPITAL
Warfarin Patient Education
Department of Pharmacy Services
[redacted] Road
[redacted]
Tel [redacted]
Office [redacted]

2. Health professional? [ ] yes
5. If you do NOT want your identity disclosed to the manufacturer

Mail to: MEDWATCH
5600 Fishers Lane
Rockville, MD 20852-9787
or FAX to: 1-800-FDA-0178

FDA Form 3500 (6/93)

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

Individual Safety Report

3703849-3-00-01

141166

MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

FOR VOLUNTARY reporting by health professionals of adverse events and product problems

FDA Use Only

Triage unit sequence #

A Patient Information

1. Patient identifier	2. Age at time of event: 85 or Date of birth:	3. Sex	4. Weight
119		☒ female ☐ male	0 lbs or 0 kgs

In Confidence

B Adverse event or product problem

1. ☒ Adverse event and/or ☐ Product Problem

2. Outcomes attributed to adverse event (Check all that apply)

☐ death (mo/day/yr)
☐ life-threatening
☐ hospitalization - initial or prolonged
☐ disability
☐ congenital anomaly
☐ required intervention to prevent permanent impairment/damage
☒ other: Required Hospitalization

3. Date of event: 03/29/2001 (mo/day/yr)

4. Date of this report: 04/03/2001 (mo/day/yr)

5. Describe event or problem

REACTION: UPPER GI BLEED
Patient known to clinic. HCT was 36 on 3/12 when seen in ER for separate problem.
On admission on Dilantin 100mg qhs, Synthroid 75 mcg qd, Premarin 0.625 mg qd, ASA 81mg, Zestril 10mg ., Adalat 90mg, Fosamax 10mg qd, Plavis 75mg + flovent and Combivent. Fosamax started around 10/99 Hx osteoporosis with compression fractures, kyphosis and scholosis. Patient on ASA 81mg already when Fosamax started. Patient was carefully educated on Fosamax administration cautions.
3/29/01 Presented to the clinic with 2 days of dark stool without hematochezie, hematemesis or abdominal pain. Noted more tired and SOB than usual. HCT now 22.2. BP 119/64. Rectal exam showed melenic stool. T&C 4 units PRBC, and give 3 units stat.
3/31/01 HCT=39.4, HGB=13.0
3/31 2 Black tarry stools overnight but not diarrhea
4/1 EGD showed erosive gastritis in antrum and 0.5 to 0.75 cm ulcer in the duodenum with surroundign scarring and duodenitis. H pylori studeis pending at discharge with f/u from primary care physician

6. Relevant tests/laboratory data, including dates

Discharged on Prilosec 20mg qd — Discharged off aspirin + off Fosamax.

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

C Suspect medication(s)

1. Name (give labeled strength and mfr/labeler, if known)
#1 alendronate, aspirin, plavix
#2

2. Dose, frequency, and route used
#1 10mg qd, 81mg qd, 75mg qd
#2

3. Therapy dates (if unknown, give duration) from/to (or best estimate)
#1
#2

4. Diagnosis for use (indication)
#1 Osteoporosis, stroke prevention
#2

5. Event abated after use stopped or dose reduced
#1 ☐ yes ☐ no ☐ N/A
#2 ☐ yes ☐ no ☐ N/A

6. Lot # (if known)
#1
#2

7. Exp. date (if known)
#1
#2

8. Event reappeared after reintroduction
#1 ☐ yes ☐ no ☐ N/A
#2 ☐ yes ☐ no ☐ N/A

9. NDC Number (for product problems only)

10. Concomitant medical products and therapy dates (exclude treatment of event)

D Suspect medical device

1. Brand name
2. Type of device
3. Manufacturer name and address

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4. Operator of device
☐ health professional
☐ lay user/patient
☐ other:

5. Expiration date (mo/day/yr)

6.
model #
catalog #
serial #
lot #
other #

7. If implanted, give date (mo/day/yr)

8. If explanted, give date (mo/day/yr)

9. Device available for evaluation? (Do not send to FDA)
☐ yes ☐ no ☐ returned to manufacturer on

10. Concomitant medical products and therapy dates (exclude treatment of event)

E Reporter (see confidentiality section)

1. Name, address, and phone #
[redacted], Pharm D
[redacted] Pharmacy

2. Health professional? ☒ yes ☐ no

3. Occupation: Pharmacist

4. Also reported to
☐ manufacturer
☐ user facility
☐ distributor

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box. ☒

Mail to: MedWatch
5600 Fishers Lane
Rockville, MD 20852-9787

or FAX to: 1-800-FDA-0178

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

CTV141166

DSS

MEDWATCH

Individual Safety Report

3703918-8-00-01

For VOLUNTARY reporting health professionals of adverse events and product problems

Page ___ of ___

CBR

Form Approved: OMB No. 0910-0291 Expires: 12/31/ See OMB statement on rever

FDA Use Only

Triage unit sequence # 141207

A. Patient information

1. Patient identifier	2. Age at time of event: or Date of birth:	3. Sex	4. Weight
[redacted] In confidence	78	☑ female ☐ male	___ lbs or 41 kgs

B. Adverse event or product problem

1. ☑ Adverse event and/or ☐ Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)
- ☐ death ___ (mo/day/yr)
- ☐ life-threatening
- ☑ hospitalization – initial or prolonged
- ☐ disability
- ☐ congenital anomaly
- ☑ required intervention to prevent permanent impairment/damage
- ☐ other: ___

3. Date of event (mo/day/yr): 12/29/00

4. Date of this report (mo/day/yr): 4-2-01

5. Describe event or problem

Suspected Drug: Enoxaparin 30mg SQ qd + ASA qd (dose not given)
Reaction: Hematemesis, severe anemia, UGI bleed (1)
PMH: PSVT, HTN, migraines, osteoarthritis, cataracts, hypercholesterolemia, depression, non-ulcer dyspepsia, recurrent CVA (on Coumadin in past but erratic PTs, switched to Enoxaparin recently), multiple infarct dementia
HPI: 78 yo F, 60", 41kg, presented 12/29 with c/o dark stools x past 2 weeks, weakness, unable to walk since 12/25.

Epistaxis x past few days. VS BP 95/63, HR 102, R 22, O2 sat 94. Black stool strongly heme +, NG tube: bloody material in stomach. Per GI consult: UGI bleed likely given chronic ASA ingestion aggravated by Enoxaparin, as well as probable vit K depletion
Labs: initial EKG: sinus tach + inferolateral ST depression, CPKs NL, WBC 26.5H, Hgb 4.5C, Hct 13C, Plt 449K, N 85, L 5, PT 23.1 H, INR 3.11, PTT 44, Na 137, K 4.2 CO2 14.8L, Cl 108L, Gluc 199H, BUN 60H, SCr 1.8H, BUN/SCr = 38.3, Digoxin 1 ng/ml, H pylori negative
SH/FH: No alcohol or tobacco use
Allergies: NKA (Hydrocodone – n/v, Verapamil-constipation)
Meds: Robaxin 500mg po q8h prn, Lanoxin 0.125mg po qd, Lescol 40mg po qd, Lovenox 30mg SQ qd, ASA qd, Cimetidine 400mg po qd, Multivitamin qd, Vit C/E/Ca qd, Lopid 600mg po qd, Toprol XL 50mg po qd, Darvocet-N 100 1 po q 6-8 h prn, Phenergan 25mg po prn
Treatment: Admit to hospital, O2 per NC, IV NS, 4 units PRBCs, Vitamin K 2.5mg po , GI consult, EGD, Pepcid, Phenergan, Cardiology consult: no MI, Per EGD: shallow ulcer confined to apex of duodenal bulb with minimal to mild oozing, hiatal hernia, probable Barrett's esophagus
Outcome: Discharged 1/1/01 in improved condition on Lanoxin, Prevacid, Toprol, KCl, Sorbitol and Plavix 75mg po qd

CTV141207

C. Suspect medication(s)

1. Name (give labeled strength & manufacturer, if known):
#1 Enoxaparin 30mg
#2 ASA qd

2. Dose, frequency & route used:
#1 30mg SQ qd
#2 unk dose qd

3. Therapy dates (if unknown, give duration):
#1 recently
#2

4. Diagnosis for use (indication):
#1 hx CVA
#2 hx CVA

5. Event abated after use stopped or dose reduced:
#1 ☑ yes ☐ no ☐ doesn't apply
#2 ☐ yes ☐ no ☐ doesn't apply

6. Lot # (if known):
#1
#2

7. Exp. date (if known):
#1
#2

8. Event reappeared after reintroduction:
#1 ☐ yes ☐ no ☐ doesn't apply
#2 ☐ yes ☐ no ☐ doesn't apply

9. NDC # (for product problems only):
- -

10. Concomitant medical products and therapy dates (exclude treatment of event):
see med list

D. Suspect medical device

1. Brand name

2. Type of device

3. Manufacturer name & address

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4. Operator of device
- ☐ health professional
- ☐ lay user/patient
- ☐ other: ___

5. Expiration date (mo/day/yr)

6.
model # ___
catalog # ___
serial # ___
lot # ___
other # ___

7. If implanted, give date (mo/day/yr)

8. If explanted, give date (mo/day/yr)

9. Device available for evaluation? (Do not send to FDA)
☐ yes ☐ no ☐ returned to manufacturer on ___ (mo/day/yr)

10. Concomitant medical products and therapy dates (exclude treatment of event)

E. Reporter (see confidentiality section on back)

1. Name, address & phone #
[redacted] RPh [redacted] CA [redacted]

2. Health professional? ☑ yes ☐ no

3. Occupation: Pharmacist

4. Also reported to
- ☐ manufacturer
- ☐ user facility
- ☐ distributor

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box. ☒

Mail to: MEDWATCH, 5600 Fishers Lane, Rockville, MD 20852-9787 or FAX to: 1-800-FDA-0178

FDA Form 3500 (5/93)

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

3703925-5-00-01

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VOLUNTARY
...ith professional or adverse
...ents and product problems

Form Approved: OMB No. 0910-0291 Expires 12-31-94
See OMB statement on reverse.

FDA Use Only
Triage unit sequence # 141188

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page of

A. Patient information

1. Patient identifier [redacted]
2. Age at time of event: 63 or Date of birth:
3. Sex: ☐ female ☒ male
4. Weight: ____ lbs or ____ kgs

B. Adverse event or product problem

1. ☒ Adverse event and/or ☐ Product problem (e.g., defects/malfunctions)
2. Outcomes attributed to adverse event (check all that apply)
   ☐ death
   ☐ life-threatening
   ☒ hospitalization - initial or prolonged
   ☐ disability
   ☐ congenital anomaly
   ☐ required intervention to prevent permanent impairment/damage
   ☐ other
3. Date of event: 2/11/01
4. Date of this report: 4/6/01
5. Describe event or problem:

6. Relevant tests/laboratory data, including dates

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

CTV141188

C. Suspect medication(s)

1. Name (give labeled strength & manufacturer if known)
   #1 [redacted]
   #2 ASA
2. Dose, frequency & route used
   #1 [redacted]
   #2
3. Therapy dates (do not use "unknown")
   #1 [redacted]
   #2
4. Diagnosis for use (indication)
   #1
   #2
5. Event abated after use stopped or dose reduced
   #1 ☒ yes ☐ no ☐ doesn't apply
   #2 ☒ yes ☐ no ☐ doesn't apply
6. Lot #
   #1
   #2
7. Exp. date
   #1
   #2
8. Event reappeared after reintroduction
   #1 ☐ yes ☐ no ☒ doesn't apply
   #2 ☐ yes ☐ no ☒ doesn't apply
9. NDC # (for product problems only)
10. Concomitant medical products (and therapy dates for adverse event reported)

D. Suspect medical device

1. Brand name
2. Type of device
3. Manufacturer name & address

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MEDWATCH CTU

4. Operator of device
   ☐ health professional
   ☐ lay user/patient
   ☐ other
5. Expiration date
6. model #
   catalog #
   serial #
   lot #
   other #
7. If implanted, give date
8. If explanted, give date
9. Device available for evaluation? (Do not send to FDA)
   ☐ yes ☐ no ☐ returned to manufacturer on
10. Concomitant medical products (including dates of use for adverse event)

E. Reporter (see confidentiality section on back)

1. Name, address & phone #
   [redacted]
2. Health professional? ☒ yes ☐ no
3. Occupation: PA
4. Also reported to
   ☐ manufacturer
   ☒ user facility
   ☐ distributor
5. If you do NOT want your identity disclosed to the manufacturer, place an X in this box. ☐

FDA

Mail to: MEDWATCH
5600 Fishers Lane
Rockville, MD 20852-9787

or FAX to:
1-800-FDA-0178

FDA Form 3500 (6/93)

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

FORM FDA 3500
Individual Safety Report

3707352-6-00-01

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

)LUNTARY reporting
h professionals of adverse
s and product problems

Page ___ of ___

Form Approved: OMB No. 0910-0291 Expires:12/31/04
See OMB statement on reverse.

FDA Use Only
Triage unit sequence #: 141575

A. Patient information

1. [redacted] identifier: 261763 In confidence
2. Age at time of event: 66 YO or Date of birth:
3. Sex: ☐ female ☒ male
4. Weight: 230 lbs or ___ kgs

B. Adverse event or product problem

1. ☐ Adverse event and/or ☐ Product problem (e.g., defects/malfunctions)
2. Outcomes attributed to adverse event (check all that apply)
   - ☐ death ___ (mo/day/yr)
   - ☐ life-threatening
   - ☒ hospitalization – initial or prolonged
   - ☐ disability
   - ☐ congenital anomaly
   - ☐ required intervention to prevent permanent impairment/damage
   - ☐ other ___
3. Date of event (mo/day/yr): 2/20/00
4. Date of this report (mo/day/yr): 4/17/01
5. Describe event or problem

- upper GI bleed - severe anemia, multiple small gastric ulcers and erosions - acute duodenal ulcer - Hiatus Hernia
- packed cells - 3 units of blood given
- Pepcid IV drip - iron supplement given

6. Relevant tests/laboratory data, including dates

- esophagogastroduodenoscopy
- Hg = 8.2 HCT = 22.9

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

Hiatus Hernia
HTN

APR 18 2001

CTU 141575

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
   #1 Aspirin
   #2
2. Dose, frequency & route used
   #1
   #2
3. Therapy dates (if unknown, give duration) (mo/day/yr or best estimate)
   #1
   #2
4. Diagnosis for use (indication)
   #1
   #2
5. Event abated after use stopped or dose reduced
   #1 ☐ yes ☐ no ☒ doesn't apply
   #2 ☐ yes ☐ no ☐ doesn't apply
6. Lot # (if known)
   #1
   #2
7. Exp. date (if known)
   #1
   #2
8. Event reappeared after reintroduction
   #1 ☐ yes ☐ no ☐ doesn't apply
   #2 ☐ yes ☐ no ☐ doesn't apply
9. NDC # (for product problems only)
   - -
10. Concomitant medical products and therapy dates (exclude treatment of event)

D. Suspect medical device

1. Brand name
2. Type of device
3. Manufacturer name & address

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MEDWATCH CTU

4. Operator of device
   ☐ health professional
   ☐ lay user/patient
   ☐ other: ___
5. Expiration date (mo/day/yr)
6. model # ___
   catalog # ___
   serial # ___
   lot # ___
   other # ___
7. If implanted, give date (mo/day/yr)
8. If explanted, give date (mo/day/yr)
9. Device available for evaluation? (Do not send to FDA)
   ☐ yes ☐ no ☐ returned to manufacturer on ___ (mo/day/yr)

DSS

10. Concomitant medical products and therapy dates (exclude treatment of event)

APR 19 2001

E. Reporter (see confidentiality section on back)

1. Name, address & phone #
   [redacted] PharmD
   Hospital and Medical Center
   [redacted]
2. Health professional? ☒ yes ☐ no
3. Occupation: Clinical Pharmacist
4. Also reported to
   ☐ manufacturer
   ☐ user facility
   ☐ distributor
5. If you do NOT want your identity disclosed to the manufacturer, place an " X " in this box. ☐

FDA

Mail to: MEDWATCH
5600 Fishers Lane
Rockville, MD 20852-9787

or FAX to:
1-800-FDA-0178

Individual Safety Report

3708840-9-00-01

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

VOLUNTARY reporting
ıealth professionals of adverse
vents and product problems
ınternet Submission - Page 1

Form Approved: OMB No. 0910-0291 Expires: 04/30/01
See OMB statement on reverse

FDA Use Only
Triage unit sequence # 141750

A. Patient information

1. Patient identifier	2. Age at time of event:	3. Sex	4. Weight
00250774	or Date of birth: [redacted]	☑ female ☐ male	____ lbs or 66 kgs

In confidence

B. Adverse event or product problem

1. ☑ Adverse event and/or ☐ Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)
- ☐ death (mm/dd/yyyy)
- ☐ life-threatening
- ☑ hosp talization – initial or prolonged
- ☐ disabil ty
- ☐ congenital anomaly
- ☐ required intervention to prevent permanent impairment/damage
- ☐ other:

3. Date of event (mm/dd/yyyy)

4. Date of this report (mm/dd/yyyy) 04/20/2001

5. Describe event or problem
GI bleed

6. Relevant tests/laboratory data, including dates
Hbg/Hct:
13.5/42.4/11-;7.4/22-4/12-;10.1/30-4/13-
INR: 5.89-4/11-;8.15-4/12-;1.89-4/13-
endoscopy 4/12 - no active bleeding

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

APR 20 2001

C-TV141750

C. Suspect medication(s)

1. Name (Product Name)	(Labeled Strength)	(Mfr/Labeler)
#1 ASA		
#2 Warfarin		

2. Dose/Frequency/Route used	3. Therapy dates (if unknown, give duration) From	To (or best estimate)
#1 325mg / qd / Oral	#1	–
#2 2mg / bid / Oral	#2	–

4. Diagnosis for use (separate indications with commas)
#1
#2

5. Event abated after use stopped or dose reduced
#1 ☑ yes ☐ no ☐ doesn't apply
#2 ☑ yes ☐ no ☐ doesn't apply

6. Lot # (if known)
#1
#2

7. Exp. date (if known)
#1
#2

8. Event reappeared after reintroduction
#1 ☐ yes ☐ no ☐ doesn't apply
#2 ☐ yes ☐ no ☐ doesn't apply

9. NDC # (for product problems only)
– –

10. Concomitant medical products and therapy dates (exclude treatment of event)
tx. to ICU, transfused 2 units of PRBC's

D. Suspect medical device

1. Brand name

2. Type of device

3. Manufacturer name & address

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APR 23 2001

4. Operator of device
- ☐ health professional
- ☐ lay user/patient
- ☐ other:

5. Expiration date (mm/dd/yyyy)

6. model # MEDWATCH CTU
catalog #
serial #
lot #
other #

7. If implanted, give date (mm/dd/yyyy)

8. If explanted, give date (mm/dd/yyyy)

9. Device available for evaluation? (Do not send device to FDA)
☐ yes ☐ no ☐ returned to manufacturer on ____ (mm/dd/yyyy)

10. Concomitant medical products and therapy dates (exclude treatment of event)

E. Reporter (see confidentiality section on back)

1. Name [redacted] phone [redacted]
[redacted] Hospital [redacted] Ave. Inpatient Pharmacy
[redacted] United States [redacted]

DSS
APR 23 2001

2. Health professional?	3. Occupation	4. Also reported to
☑ yes ☐ no	Other Health Professional	☐ manufacturer ☐ user facility ☐ distributor

5. If you do not want your identity disclosed to the manufacturer, place an "X" in this box. ☐

FDA

Mail to: MEDWATCH
5600 Fishers Lane
Rockville, MD 20852-9787

or FAX to:
1-800-FDA-0178

FDA Form 3500

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Individual Safety Report

3710502-9-00-01

professionals of adverse and product problems

#2

Triage unit sequence # GTN 141916

Patient information

Patient identifier: [redacted]

Confidence

2. Age at time of event: 76 or Date of birth:

3. Sex: Female / Male

4. Weight: ____ lbs or ____ kgs

Adverse event or product problem

Adverse event and/or Product problem (e.g., defects/malfunctions)

Outcomes attributed to adverse event (check all that apply)

- death (mo/day/yr)
- life-threatening
- hospitalization – initial or prolonged
- disability
- congenital anomaly
- required intervention to prevent permanent impairment/damage
- other:

Date of event (mo/day/yr): 3/4/01

4. Date of this report (mo/day/yr): 3/21/01

Describe event or problem

Pt Admitted c G.I. bleed - Note as being due to combination of ASA & Plavix in Hop

Pt to go back on Plavix 2wks p Discharge

6. Relevant tests/laboratory data, including dates

3/4

PT 13.6 (11-14.2)

INR 1.34

Platelets 273 (140-440)

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

Diagnosis - G.I. bleed, CAD

NKA

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)

#1 Plavix

#2 Aspirin

2. Dose, frequency & route used

#1 75 mg po daily

#2 325 mg po daily

3. Therapy dates (if unknown, give duration)

#1 Prior to Admission

#2

4. Diagnosis for use (indication)

#1 "CAD"

#2 "CAD"

5. Event abated after use stopped or dose reduced

#1 yes / no / doesn't apply

#2 yes / no / doesn't apply

6. Lot # (if known)

#1

#2

7. Exp. date (if known)

#1

#2

8. Event reappeared after reintroduction

#1 yes / no / doesn't apply

#2 yes / no / doesn't apply

9. NDC # (for product problems only)

10. Concomitant medical products and therapy dates (exclude treatment of event)

Cardizem CD

Imdur

Aricept

D. Suspect medical device

1. Brand name

2. Type of device

3. Manufacturer name & address

4. Operator of device: health professional / lay user/patient / other:

5. Expiration date (mo/day/yr)

6. model # / catalog # / serial # / lot # / other #

7. If implanted, give date (mo/day/yr)

8. If explanted, give date (mo/day/yr)

9. Device available for evaluation? (Do not send to FDA) yes / no / returned to manufacturer on (mo/day/yr)

10. Concomitant medical products and therapy dates (exclude treatment of event)

Severity level 3

E. Reporter (see confidentiality section on back)

1. Name, address & phone #: [redacted], R.Ph, Hospital

2. Health professional? yes / no

3. Occupation: Pharmacist

4. Also reported to: manufacturer / user facility / distributor

5. If you do NOT want your identity disclosed to the manufacturer, place an " X " in this box: X

Mail to: MEDWATCH, 5600 Fishers Lane, Rockville, MD 20852-9787 or FAX to: 1-800-FDA-0178

APR 24 2001

FDA Form 3500 (6/93)

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

GTN 141916

REPRODUCTION OF ORIGINAL SO DATABASE WILL MESH!

Individual Safety Report

3710831-9-00-01

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of ____

Form Approved: OMB No. 2910-0291 Expires: 11/30/99 See OMB statement on reverse.

FDA Use Only
Triage unit
Sequence #: 142129

A. Patient information

1. Patient Identifier	2. Age at time of event: or Date of birth	3. Sex	4. Weight
118 In confidence	34	☒ female ☐ male	lbs kgs

B. Adverse event or product problem

1 ☒ Adverse event and/or ☐ Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (Check all that apply)
- ☐ death ____ (mo/day/yr)
- ☐ life-threatening
- ☒ hospitalization - initial or prolonged
- ☐ disability
- ☐ congenital anomaly
- ☐ required intervention to prevent permanent impairment/damage
- ☐ other: ____

HA

3. Date of event (mo/day/yr): 6/20/00

4. Date of this report (mo/day/yr): 4-24-01

5. Describe event or problem

Adverse reaction was -
Upper GI bleed, Hgb decreased to 3, respiratory distress

Treatment of ADR was -
DC aspirin, PRBC transfusions

Severity was - severe

Causality based on Naranjo was - 5 probable

6. Relevant tests/ laboratory data, including dates

Allergies - PCN

- ☐ Due to known drug allergy
- ☑ Due to drug interaction
- ☐ Due to dose related reaction

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/ renal dysfunction, etc.)

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C. Suspect medication(s)

1. Name (give labeled strength, mfr/labeler, if known)
- #1 Aspirin
- #2 Alcohol

2. Dose, frequency, route used
- #1 see above
- #2 see above

3. Therapy dates (if unknown, give duration)
- #1
- #2

4. Diagnosis for use (indication)
- #1
- #2

5. Event abated after use stopped or dose reduced
- #1 ☒ yes ☐ no ☐ doesn't apply
- #2 ☐ yes ☐ no ☒ doesn't apply

6. Lot #
- #1
- #2

7. Exp date
- #1
- #2

8. NDC# (for product problems only)

5. Event reappeared after reintroduction
- #1 ☐ yes ☐ no ☒ doesn't apply
- #2 ☐ yes ☐ no ☒ doesn't apply

10. Concomitant medical products and therapy dates (exclude treatment of event)

D. Suspected medical device

[redacted]

E. Reporter (see confidentiality section on back)

1. Name, Address, phone #
[redacted] PharmD
[redacted] Medical Center [redacted]

2. Health professional? ☒ yes ☐ no

3. Occupation: Drug Info Specialist

4. Also reported to
- ☐ manufacturer
- ☐ user facility
- ☐ distributor

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box. ☒

FDA

Mail to: MEDWATCH
5600 Fishers Lane
Rockville, MD 20852-9787

or FAX to:
1-800-FDA-0178

APR 25 2001

DSS

APR 26 2001

CTU 142129

Individual Safety Report

3714537-1-00-01

VOLUNTARY reporting professionals of adverse and product problems

Page 1 of 1

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Form Approved: OMB No. 0910-0291 Expires:12/31/94
See OMB statement on reverse

FDA Use Only

Triage unit sequence # 142349

A. Patient information

1. Patient identifier	2. Age at time of event: / or Date of birth:	3. Sex	4. Weight
[redacted] In confidence	77 / [redacted]	☐ female ☒ male	177 lbs or ___ kgs

B. Adverse event or product problem

1. ☒ Adverse event and/or ☐ Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)
- ☐ death ___ (mo/day/yr)
- ☐ life-threatening
- ☒ hospitalization – initial or prolonged
- ☐ disability
- ☐ congenital anomaly
- ☐ required intervention to prevent permanent impairment/damage
- ☐ other: ___

3. Date of event (mo/day/yr): 4/16/01

4. Date of this report (mo/day/yr): 4/23/01

5. Describe event or problem

Upper GI Bleed - Melena
Confusion, weakness
Received Blood Transfusion (4 units)
+ discharged on ASA
~~+ [illegible] wk course~~
~~of Plavix (per) AM~~
EGD showed approximately 13 ulcers - Antral in location per GI doctors note

6. Relevant tests/laboratory data, including dates

Admission Labs 4/16/01
H Pylori (+)
SCr = 2.0, BUN 52 K+ 5.7
Hgb 7.6 Hct 22.7 Platelet 328
Discharge Labs
Hgb 12.5 4/17/01

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

- Cardiac Stent 3 wk PTA
- CAD, HTN, Afib, ↑ Cholesterol
- Used Indocin up to 1 wk prior to admission for shoulder pain

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
#1 Plavix 75 mg PLAVIX
#2 ASA 325 mg ASPIRIN

2. Dose, frequency & route used
#1 75 mg qd
#2 325 mg qd

3. Therapy dates (if unknown, give duration) from/to (or best estimate)
#1 3 weeks
#2 Long Time Before

4. Diagnosis for use (indication)
#1 Cardiac Stent Placement
#2 CAD

5. Event abated after use stopped or dose reduced
#1 ☒ yes ☐ no ☐ doesn't apply
#2 ☐ yes ☐ no ☐ doesn't apply

6. Lot # (if known)
#1
#2

7. Exp. date (if known)
#1
#2

8. Event reappeared after reintroduction
#1 ☐ yes ☐ no ☒ doesn't apply
#2 ☐ yes ☐ no ☐ doesn't apply

9. NDC # (for product problems only)
- -

10. Concomitant medical products and therapy dates (exclude treatment of event)

Lipitor, Lopid, Atenolol, Atrovent
Unclear but possibly received Indocin in recent days PTA

D. Suspect medical device

1. Brand name

2. Type of device

3. Manufacturer name & address

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4. Operator of device
- ☐ health professional
- ☐ lay user/patient
- ☐ other: ___

5. Expiration date (mo/day/yr)

6. Model # [redacted]
Catalog # ___
Serial # ___
Lot # ___
Other # ___

7. If implanted, give date (mo/day/yr)

8. If explanted, give date (mo/day/yr)

9. Device available for evaluation? (Do not send to FDA)
☐ yes ☐ no ☐ returned to manufacturer on ___ (mo/day/yr)

10. Concomitant medical products and therapy dates (exclude treatment of event)

E. Reporter (see confidentiality section on back)

1. Name, address & phone #
[redacted]
PHARM.D., RPh
MEDICAL DSS
MAY 02 2001

2. Health professional? ☒ yes ☐ no

3. Occupation: PHARMACIST

4. Also reported to
- ☐ manufacturer
- ☒ user facility
- ☐ distributor

5. If you do NOT want your identity disclosed to the manufacturer, place an " X " in this box. ☐

Mail to: MEDWATCH, 5600 Fishers Lane, Rockville, MD 20852-9787
or FAX to: 1-800-FDA-0178

FDA

FDA Form 3500 (6/98) CTU 142349

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Individual Safety Report

3717548-5-00-01

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Internet Submission - Page 1

Form Approved: OMB No. 0910-0291 Expires: 04/30/3
See OMB statement on reverse

FDA Use Only

Triage unit sequence # 142693

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

A. Patient information

1. Patient identifier	2. Age at time of event:	3. Sex	4. Weight
3550	77 Years or Date of birth:	☐ female ☑ male	lbs or 70 kgs

In confidence

B. Adverse event or product problem

1. ☑ Adverse event and/or ☐ Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)
- ☐ death (mm/dd/yyyy)
- ☐ life-threatening
- ☑ hospitalization – initial or prolonged
- ☐ disability
- ☐ congenital anomaly
- ☑ required intervention to prevent permanent impairment/damage
- ☐ other:

3. Date of event (mm/dd/yyyy): 03/29/2001

4. Date of this report (mm/dd/yyyy): 05/03/2001

5. Describe event or problem

Patient who failed to notify anticoagulation provider at first sign of tarry stools developed GI bleed, dehydration, and hyperkalemia secondary to elevated INR -5.9-.

6. Relevant tests/laboratory data, including dates

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

1. Congestive heart failure. 2. Atherosclerotic heart disease. 3. Atrial fibrillation, on Coumadin. 4. Chronic renal insufficiency with BUN in the low 100s. 5. Type 2 diabetes, on oral agents. 6. Bradycardia. 7. Hypertension.

CTV142693

C. Suspect medication(s)

1. Name (Product Name)	(Labeled Strength)	(Mfr/Labeler)
#1 Warfarin	2.5mg	DuPont
#2 ASA	81mg	

2. Dose/Frequency/Route used	3. Therapy dates (if unknown, give duration) From – To (or best estimate)
#1 2.5mg / qD / Oral	#1 12/19/1996 - 03/29/2001
#2 81mg / qD / Oral	#2 07/28/1997 - 03/29/2001

4. Diagnosis for use (separate indications with commas)
- #1 A-Fib.
- #2 ASHD

5. Event abated after use stopped or dose reduced
- #1 ☑ yes ☐ no ☐ doesn't apply
- #2 ☑ yes ☐ no ☐ doesn't apply

6. Lot # (if known)
- #1
- #2

7. Exp. date (if known)
- #1
- #2

8. Event reappeared after reintroduction
- #1 ☐ yes ☑ no ☐ doesn't apply
- #2 ☐ yes ☑ no ☐ doesn't apply

9. NDC # (for product problems only)
- –
- –

10. Concomitant medical products and therapy dates (exclude treatment of event)

Amlodipine, Lisinopril, doxazosin, KCl, digoxin, Furosemide, Metolazone, glipizide, nephrology vitamin.

D. Suspect medical device

1. Brand name

2. Type of device

3. Manufacturer name & address

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4. Operator of device
- ☐ health professional
- ☐ lay user/patient
- ☐ other:

5. Expiration date (mm/dd/yyyy)

6. model # MEDWATCH CTU
- catalog #
- serial #
- lot #
- other #

7. If implanted, give date (mm/dd/yyyy)

8. If explanted, give date (mm/dd/yyyy)

9. Device available for evaluation? (Do not send device to FDA)
☐ yes ☐ no ☐ returned to manufacturer on (mm/dd/yyyy)

10. Concomitant medical products and therapy dates (exclude treatment of event)

E. Reporter (see confidentiality section on back)

1. Name [redacted] PharmD
VA PSHCS, 1660 S. Columbian Way
Seattle Washington 98108
United States [redacted]ed.va.gov

phone # [redacted]

2. Health professional? ☑ yes ☐ no

3. Occupation: Pharmacist

4. Also reported to
- ☐ manufacturer
- ☐ user facility
- ☐ distributor

5. If you do not want your identity disclosed to the manufacturer, place an "X" in this box. ☑

FDA

Mail to: MEDWATCH
5600 Fishers Lane
Rockville, MD 20852-9787

or FAX to: 1-800-FDA-0178

FDA Form 3500

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Individual Safety Report

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THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

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Internet Submission - Page 1 1 of 2

Form Approved: OMB No. 0910-0291 Expires: 01/31/2003
See OMB statement on reverse

FDA Use Only

Triage unit sequence # 142751

A. Patient information

1. Patient identifier	2. Age at time of event:	3. Sex	4. Weight
[redacted] In confidence	81 Years or Date of birth:	☑ female ☐ male	lbs or kgs

B. Adverse event or product problem

1. ☑ **Adverse event** and/or ☐ **Product problem** (e.g., defects/malfunctions)

2. **Outcomes attributed to adverse event** (check all that apply)
- ☐ death (mm/dd/yyyy)
- ☐ life-threatening
- ☑ hospitalization – initial or prolonged
- ☐ disability
- ☐ congenital anomaly
- ☐ required intervention to prevent permanent impairment/damage
- ☐ other:

3. **Date of event** (mm/dd/yyyy): 01/25/2001

4. **Date of this report** (mm/dd/yyyy): 05/04/2001

5. **Describe event or problem**

81 year old African American female presented to the physicians office with complaints of dark stool for 24 hours prior. Patient was referred to the Emergency Room. Medical History: Arthiritis, HTN, CAD, Hypothyroidism. Patient was started on Aspirin and Celebrex 15 days prior to admission. In ER - Patient had black, maroon-colored blood in rectum, guiac + stool. Endoscopy indicated a 1cm pyloric ulcer, no active bleeding. On Physical Exam: Patient denied abdominal pain, CP/SOB, dysuria, cough. During Hospital course, patient received 3 units PRBCs. Colonoscopy performed and WNL. NSAIDs and HTN meds were held. Patient meds during hospitalization: isosorbide dinitrate 10mg TID, omeprazole 40mg BID, levothyroxine 0.025mg QD. Patient was discharged 1/30/01.

6. **Relevant tests/laboratory data,** including dates

1/25/01 WBC 14.7; 1/26/01 WBC 13.1; 1/28/01 WBC 9.1; 1/29/01 WBC 8.8; 1/30/01 WBC 8.2. 1/25/01 RBC 2.48; 1/26/01 RBC 2.14; 1/27/01 RBC 3.53; 1/28/01 RBC 3.25; 1/29/01 RBC 3.5. 1/25/01 Hgb 8.2; 1/26/01 Hgb 11.0; 1/27/01 Hgb 11.4; 1/28/01 10.7; 1/29/01 Hgb 11.4; 1/30/01 Hgb 10.3. 1/25/01 Hct 24; 1/26/01 Hct 20.8; 1/27/01 Hct 32.3; 1/28/01 Hct 30.2; 1/30/01 Hct 30.1.

7. **Other relevant history, including preexisting medical conditions** (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

81 yo African American female ambulates with a rolling walker. NKDA. Denies current tobacco and alcohol use. Patient stated that she had esophagogastroduodenoscopy more than 5 years ago and was normal. Patient stated that she started taking Celebrex and Aspirin about 15 days prior to this event.

C. Suspect medication(s)

1. Name (Product Name)	(Labeled Strength)	(Mfr/Labeler)
#1 Celebrex	200 mg	
#2 Aspirin	325 mg	

2. Dose/Frequency/Route used	3. Therapy dates (if unknown, give duration) From	To (or best estimate)
#1 200 mg / QD / Oral	#1 01/10/2001	01/25/2001
#2 325 mg / QD / Oral	#2 01/10/2001	01/25/2001

4. **Diagnosis for use** (separate indications with commas)
- #1 Arthritis
- #2 Arthritis ,and presumably HTN/CAD

5. **Event abated after use stopped or dose reduced**
- #1 ☑ yes ☐ no ☐ does n't apply
- #2 ☑ yes ☐ no ☐ does n't apply

6. **Lot #** (if known)
- #1
- #2

7. **Exp. date** (if known)
- #1
- #2

8. **Event reappeared after reintroduction**
- #1 ☐ yes ☐ no ☑ does n't apply
- #2 ☐ yes ☐ no ☑ does n't apply

9. **NDC #** (for product problems only)
- –
- –

10. **Concomitant medical products** and therapy dates (exclude treatment of event)

Synthroid 0.025 mg QD, Isordil 10 mg TID, Norvasc 10 mg QD, Demedex 10 QD -as listed on admission-

D. Suspect medical device

1. **Brand name**

2. **Type of device**

3. **Manufacturer name & address**

4. **Operator of device**
- ☐ health professional
- ☐ lay user/patient
- ☐ other:

5. **Expiration date** (mm/dd/yyyy)

6. model # RECEIVED
catalog # MAY 07 2001
serial #
lot # MEDWATCH CTU
other #

7. **If implanted, give date** (mm/dd/yyyy)

8. **If explanted, give date** (mm/dd/yyyy)

9. **Device available for evaluation?** (Do not send device to FDA)
☐ yes ☐ no ☐ returned to manufacturer on ___ (mm/dd/yyyy)

10. **Concomitant medical products** and therapy dates (exclude treatment of event)

E. Reporter (see confidentiality section on back)

1. **Name** **phone #** [redacted]

[redacted] Hosp, [redacted] Box [redacted]

[redacted] United States

2. Health professional?	3. Occupation	4. Also reported to
☑ yes ☐ no	Pharmacist	☐ manufacturer ☐ user facility ☐ distributor

5. If you do not want your identity disclosed to the manufacturer, place an "X" in this box. ☐

FDA

Mail to: MEDWATCH 5600 Fishers Lane Rockville, MD 20852-9787 or FAX to: 1-800-FDA-0178

MAY 04 2001

FDA Form 3500

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CTU 142751

142751

MEDWATCH

For VOLUNTARY reporting by health professionals of adverse events and product problems
Internet Submission - Page 3 of 7

B6. Relevant tests/laboratory data, including dates continued

1/25/01 PT 15, INR 1.2, APTT 21. 1/27/01 Na 143, K 3.5, Gluc 80, BUN 9. 1/30/01 BUN 9, SCr 0.4, Ca 9.0, Mg 1.8, P 2.8.

Individual Safety Report

3717774-5-00-01

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

/OLUNTARY reporting
alth professionals of adverse
nts and product problems

Internet Submission - Page 1

Form Approved OMB No. 0910-0291 Expires: 04/30/03
See OMB statement on reverse

FDA Use Only

Triage unit sequence # 142766

A. Patient information

1. Patient identifier	2. Age at time of event:	3. Sex	4. Weight
0171	72 Years or Date of birth:	☐ female ☑ male	lbs or 61 kgs
In confidence			

B. Adverse event or product problem

1. ☑ **Adverse event** and/or ☐ **Product problem** (e.g., defects/malfunctions)

2. **Outcomes attributed to adverse event** (check all that apply)
- ☐ death (mm/dd/yyyy)
- ☐ life-threatening
- ☑ hospitalization – initial or prolonged
- ☐ disability
- ☐ congenital anomaly
- ☑ required intervention to prevent permanent impairment/damage
- ☐ other:

3. **Date of event** (mm/dd/yyyy): 10/26/2000

4. **Date of this report** (mm/dd/yyyy): 05/03/2001

5. **Describe event or problem**

Patient on chronic low dose ASA started clopidorel 2 weeks PTA for claudication. GI bleed requiring hospital admission. HCT on admit 16. Acute on chronic renal failure secondary to GI bleed. EGD revealed 2 gastric ulcers, injected with epinepherine.

RECEIVED
MAY 07 2001
MEDWATCH CTU

6. **Relevant tests/laboratory data,** including dates

Labs: 139 106 79 Glu 164 4.7 16
7.2 CBC: 10.9>16<279 MCV 89.5 ICa
2.14 Mg1.5 P04 5.3 PT 13/1.0/44

7. **Other relevant history, including preexisting medical conditions** (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

PMH: 1. CRI 2. HTN sec to RAS 3. DM-diet controlled 4. COPD 5. CHF/Pulm HTN: 6. hx/o GI bleed 7. hx/o nosebleeds last one 2 months ago requiring packing at ER. 8. PVD 9. HITT: ? versus drug induced thrombocytopenia 10. Ascites: tapped 12/99

C. Suspect medication(s)

1. **Name** (Product Name) (Labeled Strength) (Mfr/Labeler)
- #1 Clopidogrel / 75mg /
- #2 ASA / 81mg /

2. **Dose/Frequency/Route used**
- #1 75mg / qD / Oral
- #2 81mg / qD / Oral

3. **Therapy dates** (if unknown, give duration) From To (or best estimate)
- #1 09/28/2001 – 10/28/2001
- #2 03/26/2001 – 10/28/2001

4. **Diagnosis for use** (separate indications with commas)
- #1 Claudication.
- #2 ASHD

5. **Event abated after use stopped or dose reduced**
- #1 ☑ yes ☐ no ☐ does n't apply
- #2 ☑ yes ☐ no ☐ does n't apply

6. **Lot #** (if known)
- #1
- #2

7. **Exp. date** (if known)
- #1
- #2

8. **Event reappeared after reintroduction**
- #1 ☐ yes ☐ no ☑ does n't apply
- #2 ☐ yes ☑ no ☐ does n't apply

9. **NDC #** (for product problems only)
- – –

10. **Concomitant medical products** and therapy dates (exclude treatment of event)

D. Suspect medical device

1. **Brand name**

2. **Type of device**

3. **Manufacturer name & address**

4. **Operator of device**
- ☐ health professional
- ☐ lay user/patient
- ☐ other:

5. **Expiration date** (mm/dd/yyyy)

6.
- model #
- catalog #
- serial #
- lot #
- other #

7. **If implanted, give date** (mm/dd/yyyy)

8. **If explanted, give date** (mm/dd/yyyy)

9. **Device available for evaluation?** (Do not send device to FDA)
☐ yes ☐ no ☐ returned to manufacturer on (mm/dd/yyyy)

10. **Concomitant medical products** and therapy dates (exclude treatment of event)

E. Reporter (see confidentiality section on back)

1. **Name** [redacted] PharmD
phone # [redacted]
VA PSHCS, 1660 S. Columbian Way
Seattle Washington 98108
United States [redacted]med.va.gov

2. **Health professional?** ☑ yes ☐ no

3. **Occupation** Pharmacist

4. **Also reported to**
- ☐ manufacturer
- ☐ user facility
- ☐ distributor

5. **If you do not want your identity disclosed to the manufacturer, place an "X" in this box.** ☑

FDA

Mail to: MEDWATCH
5600 Fishers Lane
Rockville, MD 20852-9787

or FAX to:
1-800-FDA-0178

FDA Form 3500

MAY 04 2001

CTU 142766

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

Individual Safety Report

3718001-5-00-01

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

...cor, Inc.
For use by user-facilities,
...tors and manufacturers for
MANDATORY reporting

Mfr report # NSADSS2001010650
FDA Use Only

A. Patient information

1. Patient identifier: [redacted] In confidence
2. Age at time of event: 52 yr
Date of birth: [redacted]
3. Sex: [x] female [ ] male
4. Weight: UNK lbs or unk
UNK kgs

B. Adverse event or product problem

1. [x] Adverse event and/or [ ] Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)
[ ] death ____ (mo/day/yr)
[x] life-threatening
[x] hospitalization - initial or prolonged
[ ] disability
[ ] congenital anomaly
[x] required intervention to prevent permanent impairment/damage
[ ] other: ____

3. Date of event (mo/day/yr): 08/25/00
4. Date of this report (mo/day/yr): 04/11/01

5. Describe event or problem

Report received involves a subject enrolled in a Genentech Phase IIIB, randomized, open-label study comparing enoxaparin, heparin and abciximab in use in combination with TNKase in subjects with acute myocardial infarction (AMI).

A 52-year-old woman subject (#537204), weight not specified, developed a GI bleed on 25-Aug-00. The subject presented with a myocardial infarction on 24-Aug-00 and was randomized to the half-dose TNKase, abciximab and heparin arm of the study. On 25-Aug-00, six hours and 40 minutes after the study drugs were administered, the subject developed a GI bleed. The abciximab infusion was decreased by one-half dose. An aPTT was 25.5 seconds. A second episode of GI bleed occurred and the heparin and abciximab infusions were discontinued. The subject was hemodynamically unstable and was treated with volume replacement and a blood transfusion. An upper gastrointestinal endoscopy was performed on 25-Aug-00 and revealed severe distal esophagitis. A coronary angiogram was performed on 31-Aug-00 and showed multi-vessel disease.
(Cont.)

6. Relevant tests/laboratory data, including dates

(Lab data cont.

(Cont.)

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

Obesity
Hypertension, diabetes mellitus, hypercholesterolemia and PTCA without infarction

APR 19 2001

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

3500A Fix similar

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
#1 REOPRO(2 mg/mL solution)(ABCIXIMAB)
#2 HEPARIN SODIUM(HEPARIN SODIUM)

2. Dose, frequency & route used
#1 IV
#2 IV

3. Therapy dates (if unknown, give duration)
#1 08/24/00 - 08/25/00
#2 08/24/00 - 08/25/00

4. Diagnosis for use (indication)
#1 ACUTE MYOCARDIAL INFARCTION
#2 ACUTE MYOCARDIAL INFARCTION

5. Event abated after use stopped or dose reduced
#1 [ ] yes [ ] no [x] doesn't apply
#2 [ ] yes [ ] no [ ] doesn't apply

6. Lot # (if known)
#1
#2

7. Exp. date (if known)
#1
#2

8. Event reappeared after reintroduction
#1 [ ] yes [ ] no [x] doesn't apply
#2 [ ] yes [ ] no [ ] doesn't apply

9. NDC # - for product problems only (if known)

10. Concomitant medical products and therapy dates (exclude treatment of event)
1) ASPIRIN(ACETYLSALICYLIC ACID) ??/???/?? - 08/24/00
2) INSULIN(INSULIN) 08/24/00 - 08/25/00

(Cont.)

G. All manufacturers

1. Contact office - name/address (& mfring site for devices)
Centocor, Inc.
200 Great Valley Parkway
Malvern PA 19355-1307
USA
(Informing Unit)

2. Phone number: 610-889-4535

3. Report source (check all that apply)
[x] foreign
[x] study
[ ] literature
[ ] consumer
[x] health professional
[ ] user facility
[ ] company representative
[ ] distributor
[ ] other: ____

4. Date received by manufacturer (mo/day/yr): 04/05/01

5. (A)NDA # ____
IND # ____
PLA # [redacted]
pre-1938 [ ] yes
OTC product [ ] yes

6. If IND, protocol #: N2139G/1123.10

7. Type of report (check all that apply)
[ ] 5-day [x] 15-day
[ ] 10-day [ ] periodic
[x] initial [ ] follow-up # ____

8. Adverse event term(s)
1) OESOPHAGITIS
2) CORONARY ARTERY DISORDER
3) GI HAEMORRHAGE

9. Mfr. report number: NSADSS2001010650

E. Initial reporter

1. Name, address & phone #
Mr James Nickas
Genetech, Inc.
1 DNA Way
South San Francisco, CA 94080-4990

2. Health professional? [x] yes [ ] no

3. Occupation: Pharmacis

4. Initial reporter also sent report to FDA [ ] yes [ ] no [x] unk

APR 19 2001

Centocor, Inc.

Individual Safety Report

3718001-5-00-02

r use by user-facilities,
rs and manufacturers for
DATORY reporting

Page 2 of 3

Mfr report # NSADSS2001010650

LE/Dist report #

FDA Use Only

A. Patient information

1. Patient identifier	2. Age at time of event: or Date of birth:	3. Sex	4. Weight
In confidence		☐ female ☐ male	____ lbs or ____ kgs

B. Adverse event or product problem

1. ☐ Adverse event and/or ☐ Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)
- ☐ death: ____ (mo/day/yr)
- ☐ life-threatening
- ☐ hospitalization - initial or prolonged
- ☐ disability
- ☐ congenital anomaly
- ☐ required intervention to prevent permanent impairment/damage
- ☐ other: ____

3. Date of event (mo/day/yr)

4. Date of this report (mo/day/yr)

5. Describe event or problem

6. Relevant tests/laboratory data, including dates

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
#3 TENECTEPLASE
#4

2. Dose, frequency & route used
#3 20 mg, 1 in 1 time(s), IV bol
#4

3. Therapy dates (if unknown, give duration) (mo/day/yr or best estimate)
#3 08/24/00 - 08/24/00
#4

4. Diagnosis for use (indication)
#3 ACUTE MYOCARDIAL INFARCTION
#4

5. Event abated after use stopped or dose reduced
#3 ☐ yes ☐ no ☐ doesn't apply
#4 ☐ yes ☐ no ☐ doesn't apply

6. Lot # (if known)
#3
#4

7. Exp. date (if known)
#3
#4

8. Event reappeared after reintroduction
#3 ☐ yes ☐ no ☐ doesn't apply
#4 ☐ yes ☐ no ☐ doesn't apply

9. NDC # - for product problems only (if known)

10. Concomitant medical products and therapy dates (exclude treatment of event)

G. All manufacturers

1. Contact office - name/address (& mfring site for devices)

2. Phone number

3. Report source (check all that apply)
- ☐ foreign
- ☐ study
- ☐ literature
- ☐ consumer
- ☐ health professional
- ☐ user facility
- ☐ company representative
- ☐ distributor
- ☐ other: ____

4. Date received by manufacturer (mo/day/yr)

5. (A)NDA # ____
IND # ____
PLA # ____
pre-1938 ☐ yes
OTC product ☐ yes

6. If IND, protocol #

7. Type of report (check all that apply)
- ☐ 5-day ☐ 15-day
- ☐ 10-day ☐ periodic
- ☐ Initial ☐ follow-up # ____

8. Adverse event term(s):

9. Mfr. report number

E. Initial reporter

1. Name, address & phone #

DSS

MAY 2 3 2001

2. Health professional? ☐ yes ☐ no

3. Occupation

4. Initial reporter also sent report to FDA ☐ yes ☐ no ☐ unk

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

3500A Fees rule

APR 19 2001

B. Adverse event or product problem

B.5 Describe event or problem (Cont...)

The event resolved with no new episodes of GI bleed occurring since the discontinuation of the study drugs.

The investigator considers the event possibly related to study therapy.

B.6 Relevant tests/laboratory data, including dates (Cont...)

Lab Result :

Sl.No.	Test date	Test name	Test result	Normal value
1	03/25/01	ACTIVATED PARTIAL THROMBOPLASTIN TIME	29.5 sec (second)	
		ENDOSCOPY	UNK	
		upper GI// distal esophagitis	UNK	
2	03/31/01	UNK Angiogram// multi-vessel disease		

C10. Concomitant medical products

Seq No. : 1
Concomitant Medical Product : ASPIRIN(ACETYLSALICYLIC ACID)
Dose, frequency & route used : 1) unknown
Diagnosis for use(indication) : 1) UNKNOWN

Seq No. : 2
Concomitant Medical Product : INSULIN(INSULIN)
Dose, frequency & route used : 1) unknown
Diagnosis for use(indication) : 1) UNKNOWN

DSS

APR 1 9 2001

Individual Safety Report

3721893-7-00-01

Approved by FDA on 12/02/93

Mfr report # A109931

UF/Dist report #

FDA Use Only

"+" indicates item continued

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

A. Patient Information

1. Patient Identifier	2. Age at time of event:	3. Sex	4. Weight
[redacted] in confidence	72 YRS or Date of Birth: [redacted]	☒ Female ☐ Male	126.0 lbs or ____ kgs

B. Adverse event or product problem

1. ☒ Adverse event and/or ☐ Product problem (e.g. defects/malfunctions)

2. Outcomes attributed to adverse event (Check all that apply)

- ☐ death ____ (mo/day/yr)
- ☐ life-threatening
- ☒ hospitalization - initial or prolonged
- ☐ disability
- ☐ congenital anomaly
- ☒ required intervention to prevent permanent impairment/damage
- ☐ other: ____

3. Date of event: 06/--/00 (mo/day/yr)

4. Date of this report: 05/08/01 (mo/day/yr)

5. Describe event or problem

MEDICAL RECORDS RECEIVED FROM AN ATTORNEY INDICATED THAT A 72 YEAR OLD FEMALE WITH A HISTORY OF DIABETES MELLITUS, UNCONTROLLED HYPERTENSION, NON-Q-WAVE MYOCARDIAL INFARCTION, RIGHT CORONARY ARTERY DISEASE, CHRONIC RENAL FAILURE, AND FATIGUE WAS PRESCRIBED NORVASC (AMLODIPINE) 5MG DAILY FOR UNCONTROLLED HYPERTENSION FROM 13MAR00 UNTIL AN UNSPECIFIED DATE. THE PATIENT ALSO TOOK REZULIN (TROGLITAZONE) 600MG DAILY FOR DIABETES MELLITUS FROM MAR97 UNTIL MAR00, COUMADIN (WARFARIN SODIUM) IN OCT00 FOR DEEP VEIN THROMBOSIS (DVT) PROPHYLAXIS AND ASPIRIN IN MAR00 FOR AN UNKNOWN INDICATION, IN ADDITION TO OTHER CONCOMITANT MEDICATIONS.
ON 13MAR00 THE PATIENT EXPERIENCED A FLUSHED FEELING WHICH WAS THOUGHT TO BE SECONDARY TO PLENDIL (FELODIPINE). FELODIPINE THERAPY WAS DISCONTINUED AND NORVASC (AMLODIPINE) THERAPY WAS STARTED. SOME TIME IN MAR00, TROGLITAZONE THERAPY WAS DISCONTINUED. ON 28JUN00, THE PATIENT SAW HER PHYSICIAN FOR SWELLING OF HER FEET AND PAIN IN BOTH LEGS WHEN WALKING. SHE HAD ALSO BEEN FALLING ASLEEP EASILY, WHICH THE PHYSICIAN DESCRIBED AS SOMNOLENCE. THE PHYSICIAN DETERMINED THE PATIENT WAS SUFFERING FROM PERIPHERAL VASCULAR DISEASE WITH CLAUDICATION. ON 05JUL00, AN ARTERIOGRAM WAS +

6. Relevant tests/laboratory data, including dates

DEC99:
FASTING BLOOD SUGAR: 164
HEMOGLOBIN A1C: 7.4

13MAR00:
BLOOD PRESSURE 140/40
PULSE: 72
HEIGHT: 63 INCHES +

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking & alcohol use, hepatic/renal dysfunction, etc.)

DIZZINESS:
- MAR99
NICOTINE CONSUMPTION:
- SINCE 1920
HYPERTENSION:
- SINCE 1992
NAUSEA:
- 02DEC96
VOMITING: +

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)

1 NORVASC TABLETS

2 TROGLITAZONE Cont.

2. Dose, frequency & route used

1 5.00 MG TOTAL DAILY:ORAL

2 600.00 MG TOTAL

3. Therapy dates (if unknown, give duration) from/to (or best estimate)

1 03/13/00 - UNKNOWN

2 03/--/97 - 03/--/00

4. Diagnosis for use (indications)

1 UNCONTROLLED HYPERTENSION

2 DIABETES MELLITUS

5. Event abated after use stopped or dose reduced

1 ☐ yes ☒ no ☐ doesn't apply

2 ☐ yes ☒ no ☐ doesn't apply

6. Lot # (if known)

1 UNKNOWN

2 UNKNOWN

7. Exp. date (if known)

1 UNKNOWN

2 UNKNOWN

8. Event reappeared after reintroduction

1 ☐ yes ☐ no ☒ doesn't apply

2 ☐ yes ☐ no ☒ doesn't apply

9. NDC # - for product problems only (if known)

N/A

10. Concomitant medical products and therapy dates (exclude treatment of event)

GLUCOTROL XL	UNKNOWN - PRESENT
CLARITIN	UNKNOWN - PRESENT
PRINIVIL	UNKNOWN - PRESENT
XANAX	UNKNOWN - PRESENT
PREMARIN	UNKNOWN
ARTHROTEC	UNKNOWN +

G. All manufacturers

1. Contact office - name/address (& mfring site for devices)

PFIZER REGULATORY SAFETY
PFIZER PHARMACEUTICALS
235 EAST 42 STREET
NEW YORK, N.Y. 10017
U.S.A

2. Phone number: 212-573-3129

3. Report source (check all that apply)

- ☐ foreign
- ☐ study
- ☐ literature
- ☒ consumer
- ☐ health professional
- ☐ user facility
- ☐ company representative
- ☐ distributor
- ☐ other

4. Date received by manufacturer (mo/day/yr): 02/27/01

5. (A) NDA # NDA #19-787 IND # ____ PLA # ____

pre-1938 ☐ yes

OTC product ☐ yes

6. If IND, protocol #: N/A

7. Type of report (check all that apply)

- ☐ 5-day
- ☒ 15-day
- ☐ 10-Day
- ☐ periodic
- ☒ initial
- ☐ follow-up # ____

8. Adverse event term(s)

SOMNOLENCE
PURPURA
EDEMA
ANEMIA
ABNORMAL STOOLS
ASTHENIA
GASTROINTESTINAL HEMORRHAGE
COAGULATION DISORDER
ILEUS
LAB TEST ABNORMAL +

9. Mfr. report number: A109931

E. Initial reporter

1. Name, address & phone #

[redacted] SUITE [redacted]
Tel. [redacted]

DSS
MAY 14 2001

2. Health professional? ☐ yes ☒ no

3. Occupation: PARALEGAL

4. Initial reporter also sent report to FDA: ☐ yes ☐ no ☒ unk

FDA Fascimile Form 3500A

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

Individual Safety Report

3721893-7-00-02

Approved by FDA on 02/02/93

Mfr report # A109931
UF/Dist report #
FDA Use Only

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)

3 WARFARIN SODIUM

4 ASPIRIN

2. Dose, frequency & route used

3 5.00 MG TOTAL;DAILY;ORAL

4 UNKNOWN

3. Therapy dates (if unknown, give duration) from/to (or best estimates)

3 10/--/00 - PRESENT

4 03/--/00 - UNKNOWN

4. Diagnosis for use (indications)

3 DVT PROPHYLAXIS

4 INDICATION UNKNOWN

5. Event abated after use stoped or dose reduced

3 ☒ yes ☐ no ☐ doesn't apply

UNKNOWN

4 ☐ yes ☐ no ☐ doesn't apply

6. Lot # (if known)

3 UNKNOWN

4 UNKNOWN

7. Exp. date (if known)

3 UNKNOWN

4 UNKNOWN

8. Event reappeared after reintroduction

UNKNOWN

3 ☐ yes ☐ no ☐ doesn't apply

UNKNOWN

4 ☐ yes ☐ no ☐ doesn't apply

DSS

MAY 1 4 2001

Pfizer Regulatory Safety, Pfizer Pharmaceuticals - Mfr. report # A109931

B5. EVENT DESCRIPTION - Continued

PERFORMED AND REVEALED A 75% SIGNIFICANT STENOSIS OF THE RIGHT EXTERNAL ILIAC. ON 25SEP00, THE PATIENT SAW HER PHYSICIAN FOR BRUISING,LEG EDEMA AND FATIGUE. THE LEG EDEMA WAS THOUGHT TO BE SECONDARY TO AMLODIPINE. AMLODIPINE THERAPY WAS DISCONTINUED. IN JUN00 THE PATIENT HAD AN ELEVATED THYROID STIMULATING HORMONE (TSH) LEVEL OF 5.52. ON 11JUL00 THE PATIENT HAD A STENT PLACED TO THE RIGHT ILEAC ARTERY. AS OF 11JUL00 THE PATIENT CONTINUED TO COMPLAIN OF SWOLLEN FEET AND LEGS HOWEVER SHE DID NOT HAVE ANY CLAUDICATION AFTER HER STENT PLACEMENT. ECCHYMOSIS WAS NOTED ON THE PATIENT'S RIGHT ARM DURING THE PHYSICAL EXAM. ON 09OCT00, THE PATIENT WENT TO THE EMERGENCY ROOM FOR RIGHT LOWER EXTREMITY PAIN AND SWELLING AND WAS ADMITTED TO THE HOSPITAL. SHE WAS PRESUMED TO HAVE DEEP VEIN THROMBOSIS AND WAS STARTED ON HEPARIN. DOPPLER SCANS WERE NEGATIVE FOR DEEP VEIN THROMBOSIS, BUT ON 10OCT00,
THE PATIENT'S VENOGRAM WAS POSITIVE FOR DEEP VEIN THROMBOSIS. SHE WAS GIVEN COUMADIN (WARFARIN SODIUM) AS A PULMONARY EMBOLUS PROPHYLAXIS AND DEMEROL (PETHIDINE HYDROCHLORIDE) FOR HER PAIN. HER HEMOGLOBIN AND HEMATACRIT AT THAT TIME WERE 11.2 AND 32.5 RESPECTIVELY. THE PATIENT WAS DISCHARGED ON AN UNKNOWN DATE.
ON 12OCT00 SHE WAS SWITCHED FROM HEPARIN TO LOVENOX AND CONTINUED ON HER COUMADIN, BY 17OCT00 THE PATIENT FELT BETTER, HER LEG PAIN HAD IMPROVED AND HER PT AND INR WERE 19.0 AND 2.48 RESPECTIVELY.ON 23NOV00, THE PATIENT AGAIN WENT TO THE EMERGENCY ROOM WITH SWELLING OF THE RIGHT LEG AND UPPER EXTREMITY. IN THE EMERGENCY ROOM, SHE WAS NOTED TO BE MARKEDLY ANEMIC AND SUFFERING FROM HYPERPROTHROMBINEMIA AND COAGULOPATHY, WHICH WERE THOUGHT TO BE SECONDARY TO WARFARIN THERAPY. THE PATIENT'S HEMOGLOBIN AND HEMOTACRIT WERE 7.4 AND 23.4 RESPECTIVELY. THE PATIENT'S WARFARIN DOSE WAS DECREASED AND HER PLAVIX (CLOPIDOGREL) AND VIOXX (ROFECOXIB) WERE HELD. SHE WAS ADMITTED TO THE HOSPITAL FOR FURTHER OBSERVATION AND TREATMENT. THE PATIENT REPORTED EXPERIENCING BLACK STOOLS FOR TWO TO THREE WEEKS. ON 28NOV00, AN ESOPHAGOGASTRODUODENOSCOPY WAS PERFORMED AND REVEALED HIATAL HERNIA AND ANTRAL GASTRITIS. ON 29NOV00, A TOTAL COLONOSCOPY WAS ALSO PERFORMED AND SHOWED
INTERNAL HEMORRHOIDS WITH NORMAL EXAMINATION OF CECUM AND NO OBVIOUS CHRONIC PATHOLOGY TO EXPLAIN ANEMIA. THE PATIENT ALSO EXPERIENCED A GASTROINTESTINAL BLEED. TREATMENT WITH VITAMIN K (PHYTOMENADIONE) RESOLVED THE PATIENT'S COAGULOPATHY. ON 04DEC00, THE PATIENT WAS DISCHARGED IN IMPROVED AND STABLE CONDITION. ON 11DEC00 SINCE SHE CONTINUED TO HAVE EDEMA OF THE LOWER EXTREMITY AND COMPLAINED OF "VOMITING A LITTLE BLOOD" HER COUMADIN WAS DECREASED TO 5 MG 1/2 TABLET. VIOXX AND HYDROCHLOROTHIAZIDE WERE ALSO DISCONTINUED DUE TO HER GI BLEEDING. ON 19DEC00 THE PATIENT PRESENTED TO HER PHYSICIAN'S OFFICE COMPLAINING OF LEFT THIGH PAIN AND TENDERNESS. AS A RESULT, THE PATIENT WAS ADMITTED TO THE HOSPITAL FOR TREATMENT OF A DVT ON AN UNKNOWN DATE. ON 15JAN01 SHE CONTINUED TO COMPLAIN OF LEFT CALF SORENESS AND HER PT/INR " HAD BEEN FLUCTUATING A LOT." ON 11JAN01 HER PT AND INR WERE 20.3 AND 2.82 RESPECTIVELY. THE PATIENT WAS INSTRUCTED TO INCREASE HER COUMADIN TO 5 MG DAILY. ON 18JAN01 THE PATIENT CONTINUED TO COMPLAIN OF PAIN IN HER LEFT CALF , AS A RESULT THE PATIENT WAS ADMITTED TO THE HOSPITAL FOR TREATMENT OF A DVT ON AN UNKNOWN DATE. NO FURTHER INFORMATION WAS AVAILABLE AT THE TIME OF THIS REPORT.

B6. RELEVANT TESTS/LAB. DATA - Continued

WEIGHT: 126 POUNDS
HEMOGLOBIN A1C: 6.9 (NORMAL 4.5-5.7)

05JUL00:
PHYSICAL EXAM:
EXTREMITIES): 1+ EDEMA BILATERALLY. POSITIVE RIGHT FEMORAL BRUIT. DECREASED PEDAL PULSES IN THE RIGHT LOWER EXTREMITY
ARTERIOGRAM-75 % SIGNIFICANT STENOSIS OF THE RIGHT EXTERNAL ILIAC ARTERY THROMBOSIS INVOLVING THE RIGHT CALF.

29JUN00:
RBC (MIL/UL): 3.77 NORMAL RANGE (4.00-5.00)
HEMOGLOBIN (G/DL): 10.9 NORMAL RANGE (12.0-16.0)
HEMATOCRIT (%): 33.9 NORMAL RANGE (36.0-48-0)
SODIUM (MMOL/L):134 NORMAL137-145
TSH (MU/ML): 5.52 NORMAL (0.46-5.0)
HEMOGLOBIN A1C: 6.7 NORMAL RANGE LESS THAN 7

31JUL00:
ALBUMIN: 3.4 NORMAL (3.5-5.5)
CARBON DIOXIDE: 19 NORMAL (20-32)
HEMOGLOBIN A1C: 6.7

09OCT00:
HEMOGLOBIN: 11.2
HEMATOCRIT: 32.5
VENOUS DOPPLER AND VENOUS IMAGING: NO EVIDENCE OF DEEP VEIN THROMBOSIS

10OCT00:
RED CELL WHOLE BODY VENOGRAM: FINDING SUGGESTIVE OF EVIDENCE OF DEEP VEIN THROMBOSIS

01NOV00:
PT 20.3

Pfizer Regulatory Safety, Pfizer Pharmaceuticals - Mfr. report # A109931

INR: 2.82

06NOV00:

RBC (MIL/UL): 2.75 NORMAL RANGE (4.0-5.0)
HEMOGLOBIN (G/DL):7.7 NORMAL RANGE (12.-16.0)
HEMATOCRIT (%): 25.2 NORMAL RANGE: (36.0-48.0)
PROTHROMBIN TIME
(PT IN SEC): 24.1 NORMAL 11.1-12.7
INR: 3.93 NORMAL RANGE: (2.0-3.5)

24NOV00:
HEMOGLOBIN: 7.4
HEMATOCRIT: 23.4

25NOV00:
CHEST X-RAY - NO ACUTE CARDIOPULMONARY PROCESS.
PROTHROMBIN TIME (SEC): > 45 SECONDS

29NOV00:
TOTAL FIBEROPTIC COLONOSCOPY: REVEALED TWO INTERNAL HEMORRHOIDS AT 30'CLOCK AND 11 O'CLOCK.

27NOV00:
RIGHT FOOT X-RAY: FORESHORTENING OF THE 5TH METATARSAL BONE DISTALLY.

30NOV00: NON-SPECIFIC CALCIFICATIONS ARE PRESENT IN THE PELVIC REGION, MOSTLY ON THE LEFT SIDE. THERE IS A VASCULAR STENT TO THE RIGHT ILIAC REGION.

01DEC00:
CHEMISTRY:
SODIUM: 138
POTASSIUM: 3.5
CHLORIDE:103
CO2: 25
GLUCOSE: 214
BUN: 10
CREATININE: .6
PHOSPHOROUS

11DEC00:
PROTHROMBIN TIME:
PATIENT TIME: 80.2 NORMAL RANGE (9.4-12.5)
INR: 6.7 NORMAL RANGE (2.0-3.5)
HEMOGLOBIN (G/DL): 10.9
HEMATOCRIT (%): 31.6
RBC: 3.62

15DEC00:
PROTHROMBIN TIME (SEC): 14.8 NORMAL RANGE (11.1-12.7)
INR: 1.53 NORMAL RANGE: 2.0-3.5

18DEC00:
PROTHROMBIN TIME (PT): 25.3 NORMAL RANGE (11.1-12.7)
INR: 4.32 NORMAL RANGE (2.0-3.5)

28DEC00:
PT: 18.4
INR: 2.33

11JAN01:
PROTHROMBIN TIME: 20.3
INR: 2.82

01FEB01:
PROTHROMBIN TIME: 13.2 NORMAL RANGE (11.1-12.7)
INR: 1.22 NORMAL RANGE (2.0-3.5)

15FEB01
PROTHROMBIN TIME: 13.4
INR: 1.26

B7. OTHER RELEVANT HISTORY - Continued

- 02DEC96
ABDOMINAL PAIN:
- 02DEC96
CHEST PAIN:
- 03DEC96
BACK PAIN
- 03DEC96
HIATAL HERNIA:
- 04DEC96
ACUTE EROSIVE GASTRITIS:
- 04DEC96
SUPERFICIAL DUODENAL ULCERS:
- 04DEC96
RENAL CYST:
- 04DEC96
INTERNAL HEMORRHOIDS:
- 24JAN97
COLON POLYP:
- 24JAN97
PROBABLE ADHESIONS:
- 24JAN97
ALLERGY TO PENICILLIN:
- 24JAN97
ALLERGY TO MYCINS:
- 24JAN97
CONSTIPATION:
- 24JAN97
HYSTERECTOMY:
- 24JAN97
ESOPHAGITIS:
- 24JAN97
ELEVATED CARDIAC ENZYMES:
- MAR99
ACUTE NON-WAVE MYOCARDIAL INFARCTION
CARDIAC CATHETERIZATION:
- 17MAR99
UNSTABLE ANGINA:
- MAR99
MILD NONOBSTRUCTIVE CORONARY ARTERY DIS:
- 17MAR99
SMALL BOWEL OBSTRUCTION
WEIGHT LOSS:
- 24JAN97
CHRONIC RENAL FAILURE
SORE BUTTOCKS:
- 16NOV99 - FURNCLE NOTED ON LEFT BUTTOCK
GOUT:
LEFT ELBOW SWELLING
FLUSHED FEELING
HYSTERECTOMY
TUBAL LIGATION
CONGESTIVE HEART FAILURE (CHF)
FATIGUE

C10. CONCOMITANT MEDICAL PRODUCTS - Continued

VERAPAMIL	UNKNOWN - PRESENT
PRANDIN	UNKNOWN - PRESENT
HCTZ	UNKNOWN
PLENDIL	UNKNOWN - PRESENT

G8. ADVERSE EVENT TERMS - Continued

Pfizer Regulatory Safety, Pfizer Pharmaceuticals - Mfr. report # A109931

PERIPHERAL VASCULAR DISORDER
DEEP THROMBOPHLEBITIS

Individual Safety Report

3722973-2-00-01

MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

30 April 2001

For use by user-facilities, distributors and manufacturers for MANDATORY reporting Pharmacia & Upjohn, Inc.

Periodic Page 166 - 1

Relsys International, Inc.
FDA Facsimile Approval: 30-JUN-1999

Mfr report # 2001039641US

User/dist. report #

FDA Use Only

A. Patient information

1. Patient Identifier: UNK in confidence
2. Age at time of event: UNK or Date of birth: UNK
3. Sex: ☐ female ☒ male
4. Weight: UNK lbs or UNK kgs

B. Adverse event or product problem

1. ☒ Adverse event and/or ☐ Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)
☐ death ☐ disability
☐ life-threatening ☐ congenital anomaly
☐ hospitalization - initial or prolonged ☐ required intervention to prevent permanent impairment/damage
☐ other:

3. Date of event: UNK
4. Date of this report: 04/24/2001

5. Describe event or problem

gastrointestinal bleeding[Gastrointestinal haemorrhage NOS]

Case Description:
Non Serious Spontaneous Report

On 08-JAN-2001 a physician called to inquire if it was safe for a patient with a recent history of gastrointestinal bleeding to restart CELEBREX. This physician reports a patient taking CELEBREX (celecoxib) 200 mg twice daily and low dose aspirin for spinal stenosis and inflammation developed gastrointestinal bleeding. The physician suspects the gastrointestinal bleeding may be due to the low dose aspirin.

6. Relevant tests/laboratory data, including dates
NI

7. Other relevant history, including preexisting medical conditions (e.g. allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)
#1 concurrent condition, Spinal stenosis NOS
#2 concurrent condition, Inflammation NOS

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
1. CELEBREX(CELECOXIB) (continued)
2. ACETYLSALICYLIC ACID(ACETYL (continued)

2. Dose, frequency & route used
1. 200 mg, bid, oral
2. low, oral

3. Therapy dates (if unknown, give duration)
1. UNK
2. UNK

4. Diagnosis for use (indication)
1. Spinal stenosis NOS
2. Spinal stenosis NOS

5. Event abated after use stopped or dose reduced
1 ☐ yes ☐ no ☐ doesn't apply UNK
2 ☐ yes ☐ no ☐ doesn't apply UNK

6. Lot # (if known)
1. UNK
2. UNK

7. Exp. date (if known)
1. UNK
2. UNK

8. Event reappeared after reintroduction
1 ☐ yes ☐ no ☐ doesn't apply UNK
2 ☐ yes ☐ no ☐ doesn't apply UNK

9. NDC # - for product problems only (if known)

10. Concomitant medical products and therapy dates (exclude treatment of event)
NI

G. All Manufacturers

1. Contact office - name/address (& mfring site for devices)
Pharmacia
Cheryl Watton, M.D.
Safety Officer
7031-248-GDS
7000 Portage Road
Kalamazoo, MI 49001 UNITED STATES

2. Phone number: (616)833-8777

3. Report source (check all that apply)
☐ foreign
☐ study
☐ literature
☐ consumer
☒ health professional
☐ user facility
☐ company representative
☐ distributor
☐ other:

4. Date received by manufacturer: 01/08/2001

5. (A)NDA # 20998
IND #
PLA #
pre-1938 ☐ yes
OTC product ☐ yes

6. If IND, protocol #

7. Type of report (check all that apply)
☐ 5-day ☐ 15-day
☐ 10-day ☒ periodic
☒ initial ☐ follow-up #

8. Adverse event term(s)
Gastrointestinal haemorrhage NOS

9. Mfr. report number
2001039641US

E. Initial reporter

1. Name & address
[redacted] M.D.
[redacted] UNITED STATES

phone #

2. Health professional ? ☒ yes ☐ no

3. Occupation: physician

4. Initial reporter also sent report to FDA ☐ yes ☐ no ☒ unk

FDA 3500A - Facsimile

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

24-Apr-2001 15:39:00

MAY 1 2001

mission of a report does not constitute
dmission that medical personnel, user
ity, distributor, manufacturer or product
caused or contributed to the event.

Experience Report
(continued)

Additional Information

C1. Name (cont.)
Suspect Medication #1: CELEBREX(CELECOXIB) capsule
Suspect Medication #2: ACETYLSALICYLIC ACID(ACETYLSALICYLIC ACID)

Individual Safety Report

3724292-7-00-01

FAX:

PAGE 1

MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

NTARY reporting
fessionals of adverse
events and product problems

Form Approved: OMB No. 0910-0291 Expires: 12/01/2
See OMB statement on reverse

FDA Use Only — N Pad

Triage unit sequence # 143404

Page ___ of ___

A. Patient information

Patient identifier	2. Age at time of event: or Date of birth:	3. Sex	4. Weight
[redacted] In confidence	87	☒ female ☐ male	165 lbs or ___ kgs

B. Adverse event or product problem

1. ☒ Adverse event and/or ☐ Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)
- ☐ death ___ (mo/day/yr)
- ☐ life-threatening
- ☒ hospitalization – initial or prolonged
- ☐ disability
- ☐ congenital anomaly
- ☐ required intervention to prevent permanent impairment/damage
- ☐ other: ___

3. Date of event (mo/day/yr): 3/14/01

4. Date of this report (mo/day/yr): 5/15/01

5. Describe event or problem

Admitted to hospital from a assisted living facility c. gross rectal bleeding.

6. Relevant tests/laboratory data, including dates

EDG - & hiatal hernia, severe ulcerative esophagitis + duodenal ulcer probably 2° to NSAIDS.

Hct 24 on 3/14/01

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

Not known.

MAY 15 2001

CTU 143404

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
- #1 Vioxx
- #2 ASA E.C.

2. Dose, frequency & route used
- #1 12.5 mg OD
- #2 325 mg OD

3. Therapy dates (if unknown, give duration) from/to (or best estimate)
- #1 ?
- #2 ?

4. Diagnosis for use (indication)
- #1 ?
- #2 ?

5. Event abated after use stopped or dose reduced
- #1 ☒ yes ☐ no ☐ doesn't apply
- #2 ☒ yes ☐ no ☐ doesn't apply

6. Lot # (if known)
- #1
- #2

7. Exp. date (if known)
- #1
- #2

8. Event reappeared after reintroduction
- #1 ☐ yes ☐ no ☒ doesn't apply
- #2 ☐ yes ☐ no ☒ doesn't apply

9. NDC # (for product problems only)
- – –

10. Concomitant medical products and therapy dates (exclude treatment of event)

D. Suspect medical device

1. Brand name

2. Type of device

3. Manufacturer name & address

4. Operator of device
- ☐ health professional
- ☐ lay user/patient
- ☐ other: ___

5. Expiration date (mo/day/yr)

6.
- model # RECEIVED
- catalog # MAY 16 2001
- serial #
- lot # MEDWATCH CTU
- other #

7. If implanted, give date (mo/day/yr)

8. If explanted, give date (mo/day/yr)

9. Device available for evaluation? (Do not send to FDA)
☐ yes ☐ no ☐ returned to manufacturer on ___ (mo/day/yr)

10. Concomitant medical products and therapy dates (exclude treatment of event)

E. Reporter (see confidentiality section on back)

1. Name, address & phone #

[redacted] Hospital [redacted] DSS

[redacted] Ave

[redacted]

MAY 17 2001

2. Health professional?	3. Occupation	4. Also reported to
☒ yes ☐ no	pharmacist	☐ manufacturer ☐ user facility ☐ distributor

5. If you do NOT want your identity disclosed to the manufacturer, place an " X " in this box. ☒

Mail to: MEDWATCH, 5600 Fishers Lane, Rockville, MD 20852-9787 or FAX to: 1-800-FDA-0178

FDA Form 3500 (6/93)

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

Individual Safety Report

3724294-0-00-01

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

VOLUNTARY reporting
ealth professionals of adverse
ents and product problems

Page ___ of ___

Form Approved: OMB No. 0910-0291 Expires: 11/30/
See OMB statement on reverse

FDA Use Only

Triage unit sequence #: 143439

A. Patient information

1. Patient identifier: [redacted] In confidence
2. Age at time of event: 74 or Date of birth:
3. Sex: [X] female [ ] male
4. Weight: ___ lbs or ___ kgs

B. Adverse event or product problem

1. [X] Adverse event and/or [ ] Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)
   - [ ] death ___ (mo/day/yr)
   - [X] life-threatening
   - [ ] hospitalization – initial or prolonged
   - [ ] disability
   - [ ] congenital anomaly
   - [ ] required intervention to prevent permanent impairment/damage
   - [ ] other: ___

3. Date of event (mo/day/yr): 10/22/2000
4. Date of this report (mo/day/yr): 4/26/01

5. Describe event or problem

pt. experienced upper GI bleed / duodenal ulcer with resultant orthostatic hypotension. Loss of consciousness 30-45 seconds with grey pallor and HR 130's. Treated with emergent endoscopy injection and cauterization of ulcer, 3 units PRBC, omeprazole 40 mg po bid.

6. Relevant tests/laboratory data, including dates

H. pylori (+)

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

pt. on NSAID prior to hospital admission.

CTU 143439

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
   - #1 Ranitidine 75mg 5cc bid
   - #2 L C ASA 325 qd
2. Dose, frequency & route used
   - #1 75mg 5cc bid
   - #2 325 mg qd
3. Therapy dates (if unknown, give duration) from/to (or best estimate)
   - #1 10/[illegible] - 10/22
   - #2 10/19 - 10/22
4. Diagnosis for use (indication)
   - #1 ACS
   - #2 ACS
5. Event abated after use stopped or dose reduced
   - #1 [ ] yes [ ] no [ ] doesn't apply
   - #2 [ ] yes [ ] no [ ] doesn't apply
6. Lot # (if known)
   - #1
   - #2
7. Exp. date (if known)
   - #1
   - #2
8. Event reappeared after reintroduction
   - #1 [ ] yes [ ] no [ ] doesn't apply
   - #2 [ ] yes [ ] no [ ] doesn't apply
9. NDC # (for product problems only)
   - – –
10. Concomitant medical products and therapy dates (exclude treatment of event)

NSAID prior to admission, [illegible] treated unknown dose [illegible]

D. Suspect medical device

1. Brand name
2. Type of device
3. Manufacturer name & address
4. Operator of device
   - [ ] health professional
   - [ ] lay user/patient
   - [ ] other: ___
5. Expiration date (mo/day/yr)
6. model # RECEIVED
   catalog # MAY 16 2001
   serial #
   lot # MEDWATCH CTU
   other #
7. If implanted, give date (mo/day/yr)
8. If explanted, give date (mo/day/yr)
9. Device available for evaluation? (Do not send to FDA)
   - [ ] yes [ ] no [ ] returned to manufacturer on ___ (mo/day/yr)
10. Concomitant medical products and therapy dates (exclude treatment of event)

E. Reporter (see confidentiality section on back)

1. Name & address: [redacted] phone # DSS
2. Health professional? [X] yes [ ] no
3. Occupation: [illegible]
4. Also reported to
   - [ ] manufacturer
   - [ ] user facility
   - [ ] distributor
5. If you do NOT want your identity disclosed to the manufacturer, place an " X " in this box. [X]

FDA Mail to: MEDWATCH, 5600 Fishers Lane, Rockville, MD 20852-9787 or FAX to: 1-800-FDA-0178

FDA Form 3500 Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event

Individual Safety Report

3724537-3-00-01

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

)LUNTARY reporting
h professionals of adverse
s and product problems

Page 1 of 1 CDER

Form Approved: OMB No. 0910-0291 Expires: 12/31/94
See OMB statement on reverse

FDA Use Only

Triage unit sequence # 193629

A. Patient information

1. Patient identifier	2. Age at time of event:	3. Sex	4. Weight
[redacted] 52Sc In confidence	or ____ Date of birth: [redacted]	☒ female ☐ male	____ lbs or ____ kgs

B. Adverse event or product problem

1. ☒ Adverse event and/or ☐ Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)
- ☐ death ____ (mo/day/yr)
- ☒ life-threatening
- ☒ hospitalization – initial or prolonged
- ☐ disability
- ☐ congenital anomaly
- ☒ required intervention to prevent permanent impairment/damage
- ☐ other: ____

3. Date of event (mo/day/yr): 1/23/01

4. Date of this report (mo/day/yr): 2/2/01

5. Describe event or problem

55 YOF adm on 1/23 for hematemesis. Pt with hx of abdominal pain, on omeprazole. At 1am on 1/23, pt vomited black material then blood and c/o mild epigastric pain. On the way to HD the next day, pt vomited blood then vomited approx. 100ml at HD. In ER, pt c/o tongue and throat pain, dizziness, and nausea. Pt was hypotensive 100s/30s, HR= 100-110s, and an EKG showed peaked T waves. Pt treated with calcium gluconate, insulin, D50. Hgb=6.5, K=6. Pt vomited an additional 250ml blood. Melena noted. Obstructive series neg. NG lavage=2L BRB. Pt given PRBCs and started on DDAVP and ranitidine. As per sister, pt taking aspirin 2 tabs qt x 1.5 weeks for headache

6. Relevant tests/laboratory data, including dates

	1/23	1/24
Hgb	6.5	6.6
Hct	19	23
Plt	108	72
SCr		8
K	6	

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

ANH ESRD on hemodialysis
HTN
LVH
Neuropathic Pain
Anxiety
Chronic Back Pain

Allergies NKDA

CT 4/43629

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
- #1 aspirin
- #2

2. Dose, frequency & route used
- #1 2 tabs qt hr
- #2

3. Therapy dates (if unknown, give duration) from/to (or best estimate)
- #1 1/23/01 – 1/23/01
- #2

4. Diagnosis for use (indication)
- #1 Headache
- #2

5. Event abated after use stopped or dose reduced
- #1 ☒ yes ☐ no ☐ doesn't apply
- #2 ☐ yes ☐ no ☐ doesn't apply

6. Lot # (if known)
- #1
- #2

7. Exp. date (if known)
- #1
- #2

8. Event reappeared after reintroduction
- #1 ☐ yes ☐ no ☒ doesn't apply
- #2 ☐ yes ☐ no ☐ doesn't apply

9. NDC # (for product problems only)
- – –

10. Concomitant medical products and therapy dates (exclude treatment of event)

Ibuprofen, Calcium, Clonidine, Depakote, Furosemide, Nephrocaps, Acetaminophen

D. Suspect medical device

1. Brand name

2. Type of device

3. Manufacturer name & address

DSS

MAY 18 2001

4. Operator of device
- ☐ health professional
- ☐ lay user/patient
- ☐ other: ____

5. Expiration date (mo/day/yr)

6.
- model # RECEIVED
- catalog #
- serial # MAY 17 2001
- lot #
- other # MEDWATCH CTU

7. If implanted, give date (mo/day/yr)

8. If explanted, give date (mo/day/yr)

9. Device available for evaluation? (Do not send to FDA)
- ☐ yes ☐ no ☐ returned to manufacturer on ____ (mo/day/yr)

10. Concomitant medical products and therapy dates (exclude treatment of event)

E. Reporter (see confidentiality section on back)

1. Name, address & phone #

[redacted] PharmD
Hospital [redacted]
Department of Pharmacy Services
[redacted] Street [redacted]
[redacted]
Phone: [redacted]

2. Health professional? ☒ yes ☐ no

3. Occupation: Pharmacist

4. Also reported to
- ☐ manufacturer
- ☒ user facility
- ☐ distributor

5. If you do NOT want your identity disclosed to the manufacturer, place an " X " in this box. ☒

FDA

Mail to: MEDWATCH
5600 Fishers Lane
Rockville, MD 20852-9787

or FAX to:
1-800-FDA-0178

FDA Form 3500 (6/93)

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

Approved by FDA on 12/02/93

Individual Safety Report
3724841-9-00-01

Pfizer

"+" indicates item continued

Mfr report # A031696

UF/Dist report #

FDA Use Only

A. Patient Information

1. Patient Identifier: [redacted] in confidence
2. Age at time of event: UNKNOWN or Date of Birth: [redacted]
3. Sex: [X] Female [ ] Male
4. Weight: UNK lbs or ____ kgs

B. Adverse event or product problem

1. [X] Adverse event and/or [X] Product problem (e.g. defects/malfunctions)

2. Outcomes attributed to adverse event (Check all that apply)
- [ ] death ____ (mo/day/yr)
- [ ] life-threatening
- [ ] hospitalization - initial or prolonged
- [X] disability
- [ ] congenital anomaly
- [X] required intervention to prevent permanent impairment/damage
- [ ] other: ____

3. Date of event: 07/25/94 (mo/day/yr)

4. Date of this report: 05/11/01 (mo/day/yr)

5. Describe event or problem

ADDITIONAL INFORMATION REPORTED TO PFIZER ON 01MAY01 CHANGES THE CLASSIFICATION OF THIS REPORT TO SERIOUS AND DETERMINED TO BE UNEXPECTED ACCORDING TO THE USPI.
THIS 60-YEAR-OLD (CURRENT AGE) FEMALE CONSUMER REPORTS THAT SHE STARTED TAKING NORVASC (AMLODIPINE) 5MG TABLET IN 98 FOR HYPERTENSION. HER BLOOD PRESSURE PRIOR TO NORVASC TREATMENT WAS 160/85MMHG. "SHORTLY AFTER STARTING" NORVASC, IN 98, SHE EXPERIENCED SWELLING TO HER ANKLES AND "POOLING". SHE WAS TREATED WITH SUPPORT HOSE AND BABY ASPIRIN. IN 99, SHE WAS STARTED ON EVISTA (RALOXIFENE HYDROCHLORIDE) FOR UNKNOWN REASONS. IN 99, THE SWELLING WAS TREATED WITH FUROSEMIDE AND "HCTZ" WAS ADDED TO LOWER HER BLOOD PRESSURE, EVEN THOUGH SHE REPORTS THAT THE NORVASC WORKED WELL ON CONTROLLING HER BLOOD PRESSURE (BLOOD PRESSURE 130/80 SINCE NORVASC THERAPY). IN 99, SHE HAD AN ULTRASOUND OF HER LEGS, WHICH WAS NORMAL. IN 2000, SHE DID NOT TAKE NORVASC FOR 3 OR 4 DAYS BECAUSE SHE LEFT IT HOME WHEN SHE TRAVELED AND SHE EXPERIENCED FEELING LIGHTHEADED, DIZZY AND FEELING A LITTLE DISORIENTED. IN THE 3 OR 4 DAYS SHE DID NOT TAKE NORVASC THERE "MAY" HAVE BEEN SOME SLIGHT DECREASE IN IN THE SWELLING.
IN AUG00, SHE WAS STARTED ON BAYCOL (CERIVASTATIN) FOR HIGH CHOLESTEROL. ON 11SEP00, THE PHYSICIAN +

6. Relevant tests/laboratory data, including dates

UNKNOWN DATE PRIOR TO NORVASC: BLOOD PRESSURE 160/85MMHG
UNKNOWN DATE(S) AFTER NORVASC: BLOOD PRESSURE 130/80MMHG
99:ULTRASOUND OF LEGS WAS NORMAL.

FOLLOW-UP (22SEP00):
TWO ULTRASOUNDS REVEALED NO VASCULAR PROBLEM.

FOLLOW-UP (23JAN01): +

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking & alcohol use, hepatic/renal dysfunction, etc.)

HIGH CHOLESTEROL:
- PRIOR TO NORVASC THERAPY
OBESE
NONSMOKER
VARICOSE VEINS-RIGHT LEG:
- 1991
RIGHT CALF MUSCLE INJURY/PAIN:
- 11JUN93 - WHILE FILING PAPER IN BOTTOM DRAWER OF LATERAL FILE; MUSCLE SPASM 25JUN93 +

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
- # 1 NORVASC TABLETS
- # 2 MEVACOR Cont.

2. Dose, frequency & route used
- # 1 5.00 MG TOTAL:DAILY ORAL
- # 2 20.00 MG TOTAL:DAILY:ORAL

3. Therapy dates (if unknown, give duration) from/to (or best estimates)
- # 1 09/10/93 - 09/11/00
- # 2 --/--/91 - UNKNOWN

4. Diagnosis for use (indications) +
- # 1 HYPERTENSION
- # 2 HIGH CHOLESTEROL

5. Event abated after use stopped or dose reduced
- # 1 [X] yes [ ] no [ ] doesn't apply
- # 2 [ ] yes [X] no [ ] doesn't apply

6. Lot # (if known)
- # 1 UNKNOWN
- # 2 UNKNOWN

7. Exp. date (if known)
- # 1 UNKNOWN
- # 2 UNKNOWN

8. Event reappeared after reintroduction
- # 1 [ ] yes [ ] no [X] doesn't apply
- # 2 [ ] yes [X] no [ ] doesn't apply

9. NDC # - for product problems only (if known)
UNKNOWN

10. Concomitant medical products and therapy dates (exclude treatment of event)

HYDROCHLOROTHIAZIDE	UNKNOWN - 09/11/00
EVISTA	07/16/98 - --/--/98
PREDNISONE	08/25/98 - --/--/98
CORTISONE	--/--/99 - --/--/99
DIOVAN	09/11/00 - PRESENT
BAYCOL	06/13/00 - PRESENT

+

G. All manufacturers

1. Contact office - name/address (& mfring site for devices)
PFIZER REGULATORY SAFETY
PFIZER PHARMACEUTICALS
235 EAST 42 STREET
NEW YORK, N.Y. 10017
U.S.A

2. Phone number
212-573-3129

3. Report source (check all that apply)
- [ ] foreign
- [ ] study
- [ ] literature
- [X] consumer
- [X] health professional
- [ ] user facility
- [ ] company representative
- [ ] distributor
- [ ] other

4. Date received by manufacturer (mo/day/yr)
09/11/00

5. (A) NDA # NDA #19-787
IND #
PLA #
pre-1938 [ ] yes
OTC product [ ] yes

6. If IND, protocol #
N/A

7. Type of report (check all that apply)
- [ ] 5-day
- [X] 15-day
- [ ] 10-Day
- [ ] periodic
- [X] initial
- [ ] follow-up # ____

8. Adverse event term(s)
DIZZINESS
HEADACHE
VERTIGO
CONJUNCTIVITIS
TINNITUS
ABDOMINAL PAIN
NAUSEA
ECCHYMOSIS
RESPIRATORY TRACT INFECTION
BRONCHITIS +

DSS
MAY 18 2001

9. Mfr. report number
A031696

E. Initial reporter

1. Name, address & phone #
[redacted] ROAD
Tel. - [redacted] +

2. Health professional?
[ ] yes [X] no

3. Occupation
UNEMPLOYED

4. Initial reporter also sent report to FDA
[ ] yes [ ] no [X] unk

FDA Facsimile Form 3500A

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

Individual Safety Report

3724841-9-00-02

Mfr report # A031696
UF/Dist report #
FDA Use Only

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)

 # 3 EXCEDRIN

 # 4 LEVAQUIN

2. Dose, frequency & route used

 # 3 NOT SPECIFIED

 # 4 500.00 MG TOTAL DAILY:ORAL

3. Therapy dates (if unknown, give duration) from/to (or best estimates)

 # 3 UNKNOWN

 # 4 04/--/98 - UNKNOWN

4. Diagnosis for use (indications)

 # 3 INDICATION UNKNOWN

 # 4 URINARY URGENCY
BACK PAIN

5. Event abated after use stoped or dose reduced

 # 3 UNKNOWN ☐ yes ☐ no ☐ doesn't apply

 # 4 UNKNOWN ☐ yes ☐ no ☐ doesn't apply

6. Lot # (if known)

 # 3 UNKNOWN

 # 4 UNKNOWN

7. Exp. date (if known)

 # 3 UNKNOWN

 # 4 UNKNOWN

8. Event reappeared after reintroduction

 # 3 UNKNOWN ☐ yes ☐ no ☐ doesn't apply

 # 4 ☐ yes ☒ no ☐ doesn't apply

DSS

MAY 18 2000

Pfizer Regulatory Safety, Pfizer Pharmaceuticals - Mfr. report # A031696

B5. EVENT DESCRIPTION - Continued

DISCONTINUED THE NORVASC DUE TO THE EVENTS.

FOLLOW-UP (22SEP00): THE CONSUMER REPORTS SHE DEVELOPED EDEMA WHICH CAUSED A LOT OF PAIN, PRESSURE AND LIMITED HER MOBILITY. HER FAMILY PHYSICIAN SUGGESTED THAT SHE MAY HAVE A VASCULAR PROBLEM. HER PHYSICIAN RECOMMENDED SHE SEE A VASCULAR SURGEON. THE PATIENT REPORTS THAT THE VASCULAR SURGEON PERFORMED AN EXAMINATION INCLUDING 2 ULTRASOUNDS. THE VASCULAR SURGEON DID NOT THINK THERE WAS A VASCULAR PROBLEM. THE PATIENT WENT TO SEE A SECOND VASCULAR SURGEON WITH THE SAME RESULTS. THE PATIENT REPORTS THAT HER FAMILY PHYSICIAN NOW CONSIDERS IT VERY POSSIBLE THAT NORVASC HAD BEEN CAUSING THE EDEMA ALL ALONG. THE PHYSICIAN SUGGESTED THAT PATIENT STOP THE NORVASC IMMEDIATELY, WHICH SHE DID.

FOLLOW-UP (23JAN01): A PHYSICIAN SUPPLIED THE PATIENT'S MEDICAL RECORD. AS OF 08OCT98, THE MEDICAL RECORD INDICATED THAT THE OBESE PATIENT USED TO WALK ABOUT 5 MILES A DAY UNTIL RECENTLY BUT NOW SHE HAD A MOVING PAIN IN HER LEFT LEG. SHE WAS ON PREDNISONE FOR 2 WEEKS IN THE PAST AND THE PAIN MAY HAVE GOTTEN BETTER. SHE HAD NO HISTORY OF DEEP VEIN THROMBOSIS (DVT). ON PHYSICAL EXAM, THERE WAS NO EVIDENCE OF THROMBOLIC SKIN CHARACTERISTICS. THE PATIENT WAS DIAGNOSED WITH SUPPORTIVE VARICOSE VEINS. THE PATIENT WAS TAKING ASPIRIN DAILY. A DOPPLER STUDY WAS PLANNED AND THE PATIENT WAS INSTRUCTED TO WEAR SUPPORT STOCKINGS AND TO AMBULATE. ON 12OCT98, A VENOUS DOPPLER STUDY WAS ABNORMAL WITH NO EVIDENCE OF DVTS. THE PATIENT WAS ADVISED TO WEAR SUPPORT COMPRESSION STOCKINGS. THE DIAGNOSIS WAS VARICOSE VEINS WITH VENOUS INSUFFICIENCY.

FOLLOW-UP (13FEB01): A PHYSICIAN PROVIDED THE RESULTS OF TWO LOWER EXTREMITY VENOUS DUPLEX SCANS. THE FIRST SCAN, PERFORMED ON 15SEP99, WAS INDICATED FOR RIGHT LOWER EXTREMITY PAIN AND EDEMA. THE SECOND SCAN, PERFORMED ON 01DEC99, WAS INDICATED FOR RIGHT LOWER EXTREMITY EDEMA. BOTH SCANS SHOWED INCOMPETENCE OF THE COMMON FEMORAL VEIN WITH NO EVIDENCE OF DEEP VEIN THROMBOSIS IN THE RIGHT LOWER EXTREMITY.

FOLLOW-UP (29MAR01): THIS PHYSICIAN REPORTS THAT THIS HE DID NOT PRESCRIBE NORVASC (AMLODIPINE). HE TREATED HER FOR VENOUS INSUFFICENCY, WHICH MAY HAVE CONTRIBUTED TO HER SWELLING. HE PERFORMED A LOWER EXTREMITY VENOUS DUPLEX SCAN, WHICH REVEALED SWELLING IN THE RIGHT LEG AND REFLUX IN HER RIGHT COMMON FEMORAL VEIN, EVERYTHING ELSE ON THE SCAN WAS NORMAL. THE PHYSICIAN'S CONCLUSION OF THE DUPLEX IMAGING WITH COMPRESSION SHOWS NO THROMBUS IN THE COMMON FEMORAL, SUPERFICIAL FEMORAL, POPLITEAL, POSTERIOR TIBIAL, PERONEAL AND GREATER SAPHENOUS VEINS. THERE IS NO EVIDENCE OF DEEP VEIN THROMBOSIS. INCOMPETENT "CFV".

FOLLOW-UP (01MAY01): A PHYSICIAN SUPPLIED THE PATIENT'S MEDICAL RECORD. AS OF 10SEP93, THE MEDICAL RECORD INDICATED THE PATIENT WAS ON NORVASC 5MG DAILY. THE PATIENT WAS ALSO CONTINUING TO TAKE HYDRODIURIL (HYDROCHLOROTHIAZIDE) 50MG. ON 14JAN94, WHEN THE PATIENT'S CHOLESTEROL WAS 247 AND HER BLOOD PRESSURE WAS 160/100, NORVASC WAS TEMPORARILY DISCONTINUED. ON 20MAY94, NORVASC 5MG WAS RENEWED FOR THREE DOSES. ON 25JUL94, THE PATIENT'S BLOOD PRESSURE WAS 145/95 AND HER CHOLESTEROL WAS 255. THE DOSE OF MEVACOR (LOVASTATIN) 20MG WAS INCREASED TO TWO TABLETS DAILY FOR SEVEN DAYS. ON 23MAR95, THE PATIENT STATED THAT TWO WEEKS AGO SHE FELT LEFT RIB PAIN AFTER TWISTING MOTION. THE PATIENT CONTINUED TO TAKE NORVASC IN 1996 AND CAME IN FOR A FOLLOW-UP VISIT TO CHECK HER HYPERTENSION AND CHOLESTEROL ON 31JAN97. HER BLOOD PRESSURE WAS 140/80 AND SHE WEIGHED 200 POUNDS. THE PATIENT WAS INSTRUCTED TO CONTINUE NORVASC 5MG DAILY AND HYDRODIURIL FOR HYPERTENSION AND MEVACOR 20MG DAILY FOR HIGH CHOLESTEROL. SHE WAS STARTED ON HORMONE REPLACEMENT THERAPY (ESTRADIOL 1MG AND PROGESTERONE) AND WAS SENT FOR A MAMMOGRAM. SHE HAD AN UPPER RESPIRATORY INFECTION, WHICH WAS RESOLVING. ON 17FEB97, THE PATIENT COMPLAINED OF A SEVERE SORE THROAT AND WAS PRESCRIBED AMOXICILLIN 500MG. HER TEMPERATURE WAS 98.4. ON 16JUN97, THE PATIENT HAD A TEMPERATURE OF 99.5 AND COMPLAINED OF SORE THROAT, SWOLLEN GLANDS, AND "PUFFY" EYES. SHE WAS DIAGNOSED WITH ALLERGIC RHINITIS AND CONJUNCTIVITIS (HISTAMINE ALLERGIC). SHE WAS PRESCRIBED LIVOSTIN (LEVOCABASTINE) EYE DROPS FOR HER LEFT EYE AND RECEIVED 0.5CC DEPO MEDROL (METHYLPREDNISOLONE) AND ZYRTEC (CETIRIZINE).
ON 21JUL97, THE PATIENT COMPLAINED OF EXCESSIVE THIRST RECENTLY. THE DRY MOUTH WAS CONSIDERED TO BE POSSIBLY RELATED TO EXCEDRIN (ACETAMINOPHEN, CAFFEINE, ASPIRIN) USE. A URINALYSIS WAS POSITIVE FOR BLOOD (UA: 4+ BLOOD), BUT WAS NEGATIVE FOR GLUCOSE. THE PATIENT RECEIVED A FLU VACCINE ON 20NOV97. ON 10APR98, THE PATIENT EXPERIENCED URINARY URGENCY AND TOOK MACROBID (NITROFURANTOIN). HER CULTURES INDICATED SHE HAD E. COLI, BUT HER URINALYSIS WAS NEGATIVE. SHE EXPERIENCED BACK PAIN, FEVER, CHILLS AND ABDOMINAL PAIN. THE PHYSICIAN DISCONTINUED THE MACROBID AND PRESCRIBED LEVAQUIN (LEVOFLOXACIN) 500MG DAILY FOR FIVE DAYS. ON 14APR98, THE PATIENT COMPLAINED OF DIARRHEA AND WAS ADVISED TO STOP THE LEVAQUIN. ON 16JUL98, THE PATIENT WAS GIVEN EVISTA. SHE DEVELOPED PAINS IN HER LEGS AND STOPPED TAKING THE MEDICATION. THE PATIENT'S BREAST BIOPSY WAS NEGATIVE. THE PATIENT WAS GIVEN RELAFEN (NABUMETONE) DAILY FOR THE PAIN IN HER VARICOSE VEINS. ON 25AUG98, THE PATIENT LOST SIX POUNDS AND WEIGHED 206 POUNDS. HER TEMPERATURE WAS 98.8. SHE COMPLAINED OF UPPER RESPIRATORY INFECTION SYMPTOMS WITH COUGH FOR FOUR DAYS. SHE WAS DIAGNOSED WITH BRONCHITIS AND WAS PRESCRIBED AMOXIL (AMOXICILLIN) AND PREDNISONE.
ON 27AUG98, THE PATIENT RETURNED TO THE PHYSICIAN'S OFFICE WITH BLOODY SPUTUM AND DIZZINESS. THE PATIENT NOTED EXPERIENCING AN ADVERSE DRUG REACTION TO PREDNISONE (COUGH PRODUCTION OF YELLOW SPUTUM). THE PATIENT WAS PRESCRIBED HYCODAN (HYDROCODONE/HOMATROPINE) SYRUP. ON 03SEP98, THE PATIENT INDICATED SHE VOMITED ONE DAY AGO AND EXPERIENCED NAUSEA, CONGESTION AND FRONTAL HEADACHE. SHE HAD DIARRHEA AND HEMORRHOIDS WITH A SMALL AMOUNT OF RECTAL BLEEDING, WHICH RESOLVED SPONTANEOUSLY. THE PHYSICIAN RECOMMENDED HAVING A COLONOSCOPY, WHICH THE PATIENT REFUSED. THE MEDICAL RECORD ON 29SEP98 INDICATED THE PATIENT WENT TO AN ORTHOPEDIST FOR HER LEG PAIN. SHE HAS NO ARTHRITIS IN HER JOINTS. SHE WAS PRESCRIBED VOLTAREN (DICLOFENAC) 50MG TWICE DAILY AFTER MEALS AND HER RELAFEN WAS DISCONTINUED. +

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B6. RELEVANT TESTS/LAB. DATA - Continued

12OCT98: VENOUS DOPPLER STUDY WAS ABNORMAL WITH NO EVIDENCE OF DVTS, DIAGNOSIS OF VARICOSE VEINS WITH VENOUS INSUFFICIENCY; RIGHT LEG VENOUS TEMPERATURE 25.9, LEFT LEG VENOUS TEMPERATURE 28.8.

FOLLOW-UP (13FEB01): 15SEP99: LOWER EXTREMITY VENOUS DUPLEX SCAN - INCOMPETENT COMMON FEMORAL VEIN WITH NO EVIDENCE OF DEEP VEIN THROMBOSIS; NO THROMBUS IN THE COMMON FEMORAL, SUPERFICIAL FEMORAL, POPLITEAL, POSTERIOR TIBIAL, PERONEAL AND GREATER SAPHENOUS VEINS.
01DEC99: LOWER EXTREMITY VENOUS DUPLEX SCAN - NO CHANGE

FOLLOW-UP (29MAR01):
UNSPECIFIED DATE:
LOWER EXTREMITY VENOUS DUPLEX SCAN, WHICH REVEALED SWELLING IN THE RIGHT LEG AND REFLUX IN HER RIGHT COMMON FERMORAL VEIN, EVERYTHING ELSE ON THE SCAN WAS NORMAL. THE PHYSICIAN'S CONCLUSION OF THE DUPLEX IMAGING WITH COMPRESSION SHOWS NO THROMBUS IN THE COMMON FEMORAL, SUPERFICIAL FEMORAL, POPLITEAL, POSTERIOR TIBIAL, PERONEAL AND GREATER SAPHENOUS VEINS. THERE IS NO EVIDENCE OF DEEP VEIN THROMBOSIS. INCOMPETENT "CFV".

FOLLOW-UP (01MAY01):
14JAN94: CHOLESTEROL: 247MG/DL, BLOOD PRESSURE: 160/100

25JUL94: CHOLESTEROL: 255MG/DL, BLOOD PRESSURE: 145/95.

31JAN97: BLOOD PRESSURE: 140/80, WEIGHT: 200 POUNDS, GLUCOSE (NON-FASTING): 81 MG/DL (65-130), URIC ACID: 3.7MG/DL (2.6-8.1), PHOSPHATE 2.9MG/DL (2.5-4.5), CALCIUM: 9.4MG/DL (8.7-10.2), MAGNESIUM: 1.73 MEQ/DL (1.4-2.0), ALK PHOSPHATASE: 76 UNITS/L (30-162), G- GLUTAMYL TRANSPEP. 20 UNITS/L (1-78), AST (SGOT): 19 IU/L (1-45), ALT (SGPT): 25 IU/L (1-50), LD: 180 IU/L (90-250), IRON: 72MCG/DL (45-145), BUN: 16MG/DL (8-24), CREATININE: 0.8MG/DL (0.6-1.2), BUN/CREATININE RATIO: 20, TOTAL PROTEIN: 7.2 GM/DL (6.3-7.9), ALBUMIN: 4.2GM/DL (3.6-4.7), GLOBULIN: 3.0GM/DL (2.2-3.7), ALB/GLOB RATIO: 1.4 (1.0-2.0), TOTAL BILIRUBIN: 0.32MG/DL (0.2-1.1), DIRECT BILIRUBIN: 0.05MG/DL (0.0-0.2), SODIUM: 138 MMOL/L (135-144), POTASSIUM: 3.9 MMOL/L (3.4-5.2), CHLORIDE: 99 MMOL/L (94-107), WBC: 7.3 THOUS./CU.MM (3.9-11.2), RBC: 4.4 MIL/CU.MM (3.8-5.2), HGB: 12.6 GM/DL (11.6-15.5), HCT: 36.3 PERCENT (34-46), MCV: 83FL (80-98), MCH: 28.7PG (27-34), MCHC: 34.7 PERCENT (32-36), RDW: 13.6 PERCENT (11-15.5), PLATELET COUNT: 229 THOUS./CU
.MM (150-400), POLY (62.3 PCT): 4547 CU.MM (1700-8500), LYMPH (28.3 PCT): 2065 CU.MM (1000-3500), MONO (7.6 PCT): 554 CU.MM (40-900), EOS (1.3 PCT): 94 CU.MM (30-550), BASO (0.5 PCT): 36 CU.MM (0.0-125), CHOLESTEROL: 246MG/DL (160-266), CHOL PERCENTILE: 59 PERCENTILE (1-75), HDL CHOLESTEROL: 37MG/DL (49-96), CHOL/HDL RATIO: 6.6 (ASSOCIATED WITH THE HIGHEST CORONARY HEART DISEASE (CHD) RISK), TRIGLYCERIDES: 372MG/DL (50-200)

17FEB97: TEMP: 98.4

16JUN97: TEMP: 99.5

21JUL97: URINALYSIS: 4+ BLOOD, GLUCOSE NEGATIVE

10APR98: CULTURES: E. COLI, URINALYSIS: NEGATIVE

16JUL98: TSH SERUM: 2.3 MU/L (0.4-4.2), WEIGHT: 212 POUNDS, BREAST BIOPSY: NEGATIVE

25AUG98: WEIGHT: 206 POUNDS, TEMP: 98.8, LUNGS: WHEEZES/RHONCHI

06OCT98: WEIGHT: 208 POUNDS

02NOV98: MAMMOGRAPHY AND ULTRASOUND OF RIGHT BREAST: MASS LESION NOT IDENTIFIED

08DEC98: GLUCOSE (NON-FASTING): 77MG/DL (65-125), URIC ACID: 3.7MG/DL (1.7-6.1), PHOSPHATE: 3.8MG/DL (2.5-4.7), CALCIUM: 10MG/DL (8.5-10.3), MAGNESIUM: 2.07MG/DL (1.5-2.5), ALK PHOSPHATASE: 71.0 UNITS/L (30-105), GGT: 26 UNITS/L (5-55), AST (SGOT): 22 IU/L (5-35), ALT (SGPT): 29 IU/L (5-40), TOTAL LD: 189 IU/L (100-215), IRON: 66MCG/DL (35-175), BUN: 17MG/DL (7-20), CREATININE: 0.8MG/DL (0.5-1.0), BUN/CREATININE RATIO: 21.3, TOTAL PROTEIN: 7.1GM/DL (6.4-8.2), ALBUMIN: 4.2GM/DL (3.7-4.9), CALC. GLOBULIN: 2.9GM/DL (2.2-3.7), A/G RATIO: 1.45 (1.0-1.9), TOTAL BILIRUBIN: 0.34MG/DL (0.2-1.2), DIRECT BILIRUBIN: 0.13MG/DL (0.0-0.2), SODIUM: 143MMOL/L (135-144), POTASSIUM: 3.6MMOL/L (3.5-5), CHLORIDE: 102MMOL/L (99-109), CHOLESTEROL: 234MG/DL (120-215), HDL CHOLESTEROL: 36MG/DL (47-89), CHOL/HDL RATIO: 6.5, CALCULATED LDL CHOL.: 132MG/DL (57.3-146), TRIGLYCERIDES: 331MG/DL (40-199)

26JAN99: WEIGHT: 204 POUNDS

19FEB99: WEIGHT: 211 POUNDS

16MAR99: KNEE X-RAY: WITHIN NORMAL LIMITS

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01JUN99: WEIGHT: 208 POUNDS

22JUL99: WEIGHT: 210 POUNDS, BLOOD PRESSURE: 130/80, AST (SGOT): 22 IU/L (5-35), ALT (SGPT): 38IU/L (5-40), ALK PHOSPHATASE: 72 UNITS/L (30-130), GLUCOSE (NON-FASTING): 84MG/DL (65-125), CALCIUM: 9.6MG/DL (8.5-10.3), BUN: 16MG/DL (8-25), CREATININE: 0.8MG/DL (0.5-1.1), BUN/CREATININE RATIO: 20, TOTAL PROTEIN 7.1GM/DL (6.3-8.2), ALBUMIN: 4.2GM/DL (3.7-4.7), CALC. GLOBULIN: 2.9GM/DL (2.2-3.8), A/G RATIO: 1.45 (1-2), TOTAL BILIRUBIN: 0.44MG/DL (0.2-1.1), DIRECT BILIRUBIN: 0.06MG/DL (0.0-0.2), SODIUM: 141MMOL/L (136-145), POTASSIUM: 3.5MMOL/L (3.5-5.2), CHLORIDE: 103MMOL/L (99-109), CARBON DIOXIDE: 26MMOL/L (21.3-30.5), T3 UPTAKE: 35.4 PERCENT (27.8-40.7), SERUM TSH: 2.8 MU/L (0.4-4.2), T4 AS THYROXINE: 9MCG/DL (4.5-12.0), CALCULATED FREE T4: 3.22 UNITS (1.75-3.8), WBC: 6.2 THOUS./CC.MM (3.9-11.2), RBC: 4.2MIL./CU.MM (3.8-5.2), HGB: 12GM/DL (11.6-15.5), HCT: 35 PERCENT (34-46), MCV: 83 FL (80-98), MCH: 28.5PG (27-34), MCHC: 34.2 PERCENT (32-36), RDW: 14.4 PERCENT (11-15.5), MPV: 10FL (7.5-11.5), AUTO PLATELET C
OUNT: 186 THOUS./CU.MM (150-400), POLY (55.7 PCT) 3453 CU.MM (1700-8500), LYMPH (31.3 PCT): 1940 CU.MM (1000-3500), MONO (10.9 PCT): 675 CU.MM (40-900), EOS (1.1 PCT): 68 CU.MM (30-650), BASO (1.0 PCT): 62 CU.MM (0.0-125), SERUM CHOLESTEROL: 225MG/DL (120-199), HDL CHOLESTEROL: 28MG/DL (35-59), CHOL./HDL RATIO: 8.03 (3-5.5), CALCULATED LDL CHOLESTEROL: 119MG/DL (75-129, TRIGLYCERIDES: 392MG/DL (40-199)
18NOV99: WEIGHT: 206
03JAN00: WEIGHT: 212 POUNDS
JAN00 OR FEB00: MRI: POSITIVE FOR TORN MEDIAL MENISCUS (TMM)
29FEB00: WEIGHT: 204 LBS, GLUCOSE (NON-FASTING): 94MG/DL (65-125), SODIUM: 142MMOL/L (136-145), POTASSIUM: 3.2 MMOL/L(3.5-5.2), CHLORIDE: 99MMOL/L (98-109), CARBON DIOXIDE: 30MMOL/L (21-31), UREA NITROGEN: 19MG/DL (9-26), CREATININE: 0.8MG/DL (0.5-1.1), BUN/CREATININE RATIO: 23.8, URIC ACID: 3.7MG/DL (1.7-7.2), PHOSPHATE: 3.8MG/DL (2.5-4.5) CALCIUM: 10MG/DL (8.5-10.3), TOTAL CHOLESTEROL: 288MG/DL (120-199), TRIGLYCERIDES: 483MG/DL (40-199), TOTAL PROTEIN: 7.8G/DL (6.3-8.2), ALBUMIN: 4.4G/DL (3.7-4.7), CALCULATED GLOBULIN: 3.4G/DL (2.2-3.8), A/G RATIO: 1.3 (1.0-1.8), TOTAL BILIRUBIN: 0.37MG/DL (0.2-1.1), DIRECT BILIRUBIN: 0.05MG/DL (0.0-0.2), ALKALINE PHOSPHATASE: 71U/L (30-130), GGT: 31U/L (5-60), AST: 22U/L (5-35), ALT: 33U/L (5-40), LD: 186U/L (100-230), IRON: 69UG/DL (40-150), WBC: 5.6 THOUS./CU.MM (3.9-10.9), RBC: 4.43 MIL./CU.MM (3.8-5.2), HEMOGLOBIN: 12.8G/DL (11.6-15.6), HEMATOCRIT: 37.2 PERCENT (34-47), MCV: 84FL (80-98), MCH: 28.9PG (27.2-34.0), MCHC: 34.4 PERCENT (32-36), RDW: 14 PERCENT (11.0-15.5
), PLATELET COUNT: 235 THOUS./CU.MM (150-400), MPV: 9.5FL (7.5-11.5), TOTAL NEUTROPHILS: 53.7 PERCENT (38-80), TOTAL LYMPHOCYTES: 35.3 PERCENT (15-49), MONOCYTES: 8.9 PERCENT (0-13), EOSINOPHILS: 1.4 PERCENT (0-8), BASOPHILS: 0.7 PERCENT (0-2), ABSOLUTE NEUTROPHILS: 3007 CELLS/CU.MM (1700-8500), ABSOLUTE LYMPHOCYTES: 1977 CELLS/CU.MM (1000-3500), ABSOLUTE MONOCYTES: 498 CELLS/CU.MM (40-900), ABSOLUTE EOSINOPHILS: 78 CELLS/CU.MM (30-550), ABSOLUTE BASOPHILS: 39 CELLS/CU.MM (0-125), SINUS RHYTHM NORMAL ECG, VENT RATE: 82 BPM, PR INT: 186 MS, QRS DUR: 96 MS, QT/QTC: 388/427 MS, P-QRS-T AXES: 47-13-24

13JUN00: WEIGHT: 208 POUNDS, CHOLESTEROL: 274MG/DL, K: 3.02MMOL/L

11SEP00: T: 97.4, BLOOD PRESSURE: 180/105, URINALYSIS: TRACE BLOOD AND LEUKOCYTES AND WAS NEGATIVE FOR GLUCOSE

06OCT00: WEIGHT: 210 POUNDS, BLOOD PRESSURE: 150/90

20FEB00: WEIGHT: 213 POUNDS, CHOLESTEROL: 240MG/DL

B7. OTHER RELEVANT HISTORY - Continued

HYPOTHYROIDISM

C4. DIAGNOSIS FOR USE (INDICATIONS) - Continued

#4
FEVER
CHILLS
ABDOMINAL PAIN

C10. CONCOMITANT MEDICAL PRODUCTS - Continued

VITAMINS	UNKNOWN

E1. NAME AND ADDRESS OF REPORTER - Continued

[redacted] MD
[redacted] ASSOCIATES
[redacted] STREET
[redacted]
Tel. - UNKNOWN

DSS
MAY 8 200

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[redacted] SURGICAL GROUP
[redacted] AVE, STE [redacted]
[redacted]
Tel. - [redacted]

UNKNOWN
ADDRESS UNKNOWN

Tel. - UNKNOWN

[redacted] MD
[redacted] AVENUE
[redacted]

Tel. - [redacted]

G8. ADVERSE EVENT TERMS - Continued

HEMATURIA
BACK PAIN
FEVER
CHILLS
DIARRHEA
RECTAL DISORDER
ACCIDENTAL FALL
COUGH INCREASED
ANOREXIA
ABNORMAL GAIT
CONFUSION
EAR PAIN
RHINITIS
PAIN
PHARYNGITIS
URINARY URGENCY
DRY MOUTH
WEIGHT GAIN
LYMPHADENOPATHY
VOMITING
PERIPHERAL EDEMA
RECTAL HEMORRHAGE
WEIGHT LOSS
PEPTIC ULCER
VOICE ALTERATION
THIRST
HYPERLIPEMIA
RHINITIS
BONE PAIN
SKIN DISCOLORATION
POLYURIA
PERIPHERAL VASCULAR DISORDER
SPUTUM INCREASED
HYPOKALEMIA
HEMOPTYSIS
HYPERTENSION
PYURIA
RASH
BREAST NEOPLASM
HYPESTHESIA
JOINT DISORDER
URINARY TRACT INFECTION
RASH
ACCIDENTAL INJURY
EVENT UNEVALUABLE
HYPOTHYROIDISM
HYPERCHOLESTEREMIA

Pfizer Regulatory Safety, Pfizer Pharmaceuticals – Mfr. Report # A031696

B5. EVENT DESCRIPTION – Continued

On 06Oct98, the patient complained of left leg discomfort without injury and notes discoloration at times. The physician noted the patient had venous insufficiency of the left leg, ecchymosis and pain. She was advised to wear compression pants/stockings. On 02Nov98, a mammography and ultrasound of the right breast showed a mass lesion, which was not identified. The tests were ordered to be repeated in one year. On 08Dec98, the patient complained of left ear discomfort with ringing. A venous flow study was performed at a different physician's office (results unknown). The patient experienced temporomandibular pain (TMJ) pain tenderness over the left joint. Since the patient's potassium level was 3.6, K-Dur (potassium) 10meq daily was added to her antihypertensive medications consisting of Norvasc 5mg daily and Hydrochlorothiazide 50mg daily. The patient was also given Zyrtec 10mg daily for her allergic rhinitis. On 26Jan99, the patient complained of intense T-spine and dorsal discomfort. The patient also complained of stomach discomfort for one week with nausea when eating. The patient was prescribed Prilosec (omeprazole) 20mg. On 18Feb99, the patient fell while walking her dog and injured her left leg and knee. She pulled over and used ice immediately. The medical records indicate she had varicose veins in both her legs. On 19Feb99, she was given Toradol (ketorolac) intramuscularly and Voltaren XL 100mg daily. Her K-Dur dose was increased to 20meq daily. On 25Feb99, an ultrasound was performed. On 06Mar99, the patient had a productive cough and was given a prescription for Levaquin 500mg daily. The patient finished the one-week regimen, but returned to the physician's office on 15Mar99 with persistent cough. The patient complained of continued left knee pain condition, difficulty walking, limping with numbness to the left thigh. The medical records indicate the patient has been unable to work from 02Feb99 to 04Apr99. A letter from the orthopedist dated 16Mar99 indicated that a knee x-ray was within normal limits. On 19Mar99, the physician extended her disability to 19Apr99 since she still had pain and limitation of knee motion. On 01Jun99, the patient complained of left lower extremity discomfort and stated that the cortisone injection in the left knee exacerbated the discomfort. On 21Jul99, the patient met with a vascular surgeon and was diagnosed with venous insufficiency. The vascular surgeon thought her myalgias were related to her thyroid disease (patient felt tired, gaining weight, dry skin). On 18Sep99, the patient had a leg screening for peripheral vascular disease (PVD). On 18Nov99, the patient returned to the physician's office complaining of left lower extremity discomfort and was unable to ambulate comfortably. After walking one mile, the pain is exacerbated. The patient noted reddened areas on both of her ankles. The patient was prescribed Lasix (furosemide) 40mg daily. On 01Dec99, a duplex doppler indicated negative results for deep vein thrombosis (DVT). On 03Jan00, the patient complained of dry cough and congestion and was prescribed Keflex (cephalexin) 250mg three times daily. As of 29Feb00, the patient was scheduled for orthopedic surgery with general anesthesia for her right knee since a MRI result was positive for torn medial meniscus (TMM). On 21Mar00, the patient was prescribed Prilosec 20mg daily for abdominal discomfort. On 13Jun00, the patient visited the physician for a routine visit and complained of lightheadedness. The patient's cholesterol was 274mg/dl, so Mevacor was discontinued and was replaced by Baycol (cerivastatin) 0.4. On 11Sep00, the patient noted the recent death of her father and loss of her voice with hoarseness for several days. She stated she experienced excessive thirst and excessive urination. She had concerns regarding hypertension and bilateral ankle edema and had been compliant with her diuretic prescription. A urinalysis indicated trace blood and leukocytes and was negative for glucose. The patient also had transient vertigo. Due to the persistent leg edema, the patient wished to try new medication. Norvasc was discontinued and Diovan (valsartan) 80mg daily was started. Hydrodiuril was also discontinued. The patient continued to take Lasix and K-Dur for venous insufficiency and Baycol for increased cholesterol. On 14Sep00, the patient returned to the physician's office and reported experiencing adverse drug reactions of dizziness and facial outbreak with the use of Diovan. The patient notes that when using Norvasc, her blood pressure was controlled, but it caused her leg edema. The patient was started on Monopril HCT (fosinopril/hydrochlorothiazide) 10/12.5. She was given furosemide to use as needed for edema. On 06Oct00, the patient was experiencing edema in both legs since she changed medications. She was taking Lasix 40mg daily. Her Monopril HCT dose was increased to twice daily for her hypertension, but her Baycol was switched back to Mevacor 20mg daily. On 04Dec00,

Pfizer Regulatory Safety, Pfizer Pharmaceuticals – Mfr. Report # A031696

B5. EVENT DESCRIPTION – Continued

the patient complained of head congestion for three days. Her cholesterol and blood pressure were maintained and the edema had resolved in both lower extremities. The patient was prescribed Levaquin and Zyrtec. On 29Dec00, the patient complained of nausea, decreased appetite especially at night, cough, head congestion and peptic ulcer disease (PUD) for a few weeks. She was prescribed Prilosec 20mg and Claritin (loratadine) 10mg. On 20Feb00, the patient visited the physician for a blood pressure and cholesterol check. Her Monopril HCT dose was increased and she was started on Lipitor (atorvastatin) for high cholesterol.

MEDWATCH Form

APPENDIX

Individual Safety Report

3725470-3-00-01

COEF

For VOLUNTARY reporting by health professionals of adverse events and product problems

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page ___ of ___

143794

A Patient information

1. Patient identifier [redacted] In confidence
2. Age at time of event: 73 yrs or Date of birth: [redacted]
3. Sex: ☑ female ☐ male
4. Weight: ___ lbs or 47 kgs

B Adverse event or product problem

1. ☑ Adverse event and/or ☐ Product problem (e.g. defect/malfunction)
2. Outcomes attributed to adverse event (check all that apply)
☐ death ___ (mm/dd/yy)
☑ life-threatening
☐ hospitalization – initial or prolonged
☐ disability
☐ congenital anomaly
☐ required intervention to prevent permanent impairment/damage
☐ other: ___
3. Date of event (mm/dd/yy): 1/2/2001
4. Date of this report (mm/dd/yy): 1/8/2001
5. Describe event or problem

pt admitted to [redacted] SPTBOP c inferior wall non-Q MI. In Cath lab post procedure pt received plavix 300mg additional 1000 u ↑ ACT - 238 sec. Integrelin 8mg bolusesx 2 given and Integrelin drip started at 2.5ml/hr (2mg/ml) Pt had been on Lovenox 1mg/kg SQ q12 for 3 Days prior to Cath - dose held Am of Cath. LGI bleeding pm of Cath Day ↓ Hgb ↓ to 6.0 (10.1) on admit - Integ. D/C'd. IV fluids started - 2 units PRBC's Transfused

Heparin D/C at Cath

prior Vioxx use but reportedly 2 ulcers 2 weeks prior.

6. Relevant tests/laboratory data, including dates

1/3 Plts 102K
Hgb 9.4 ↓ to 6
pm 1/2
Pulse 62
BP 133/58
Hgb 6.0

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

PMH: Hypothyroidism, H/o chronic anemia
Sclerodema
Gastroenteritis
Diverticulosis
Iron deficiency
TIA
Esophageal stricture last dilated 2 wks prior - no bleeding reported at that time

C Suspect medication(s)

1. Name (give labeled strength & manufacturer, if known)
#1 Eptegrelin, PLAVIX
#2 ASA
2. Dose, frequency & route used
#1 8mg boluses x 2
#2 drip 2.5ml/hr (2mg/ml)
3. Therapy dates (if unknown, give duration)
#1 1/2/01
#2
4. Diagnosis for use (indication)
#1 Stent Insertion RCA
#2
5. Event abated after use stopped or dose reduced
#1 ☑ yes ☐ no ☐ doesn't apply
#2 ☐ yes ☐ no ☐ doesn't apply
6. Lot # (if known)
#1
#2
7. Exp. date (if known)
#1
#2
8. Event reappeared after reintroduction
#1 ☐ yes ☐ no ☑ doesn't apply
#2 ☐ yes ☐ no ☐ doesn't apply
9. NDC # (for product problems only)
10. Concomitant medical products and therapy dates (exclude treatment of event)
also on ASA, Lovenox, Chald Am & ev. Plavix

D Suspect medical device

1. Brand name [redacted]
2. Type of device
3. Manufacturer name & address
4. Operator of device ☐ health professional ☐ lay user/patient ☐ other:
5. Expiration date (mm/dd/yy)
6. RECEIVED
model # ___
catalog # ___ MAY 18 2001
serial # ___
lot # ___ MEDWATCH CTU
other # ___
7. If implanted, give date (mm/dd/yy)
8. If explanted, give date (mm/dd/yy)
9. Device available for evaluation? ☐ yes ☐ no ☐ returned to manufacturer on ___ (mm/dd/yy) (Do not send to FDA)
10. Concomitant medical products and therapy dates (exclude treatment of event)

E Reporter (confidential information)

1. Name, address & phone #
[redacted] PharmD [redacted] Heart Health System
2. Health professional? ☑ yes ☐ no
3. Occupation: Pharmacist
4. Also reported to ☐ manufacturer ☐ user facility ☐ distributor
5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box. ☐

FDA Mail to: MEDWATCH, 5600 Fishers Lane, Rockville, MD 20852-9787 or FAX to: 1-800-FDA-0178

FDA Form 3500 (6/99) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

MAY 18 2001

DSS

MAY 2 [illegible] Data Information® 97

DSS

MAY 2 2001

CTU 143794

Form approved: OMB ... 0291 Expires:12/31/ ...
See OMB statement on reverse

MEDWATCH
FDA Individual Safety Report

3725800-2-00-01

For VOLUNTARY reporting by professionals of adverse and product problems

page 1 of 1

FDA Use Only — H Pad

Triage unit sequence # 143823

A. Patient information

1. Patient identifier	2. Age at time of event: or Date of birth:	3. Sex	4. Weight
[redacted] In confidence	83 y/o	☐ female ☒ male	unk lbs or ___ kgs

B. Adverse event or product problem

1. ☒ Adverse event and/or ☐ Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)
- ☐ death (mo/day/yr)
- ☐ life-threatening
- ☒ hospitalization – initial or prolonged
- ☐ disability
- ☐ congenital anomaly
- ☐ required intervention to prevent permanent impairment/damage
- ☐ other:

3. Date of event (mo/day/yr): 4/27/00

4. Date of this report (mo/day/yr): 4/17/01

5. Describe event or problem

dark, melanotic stools – upper GI bleed requiring PRBC transfusion 2° to aspirin and anti-inflammatory therapy; cauterization of duodenal ulcer

DSS

MAY 21 2001

6. Relevant tests/laboratory data, including dates

H/H 4/30 : 8.0/23.5
5/1 : 8.8/25.7
5/3 : 9.4/27.9
5/6 : 9.7/28.6
5/7 : 9.4/28.7
4/29/00 : upper endoscopy – active bleeding ulcer

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

Allg: Sulfa, Betadine Race: Caucasian
⊕ tob, ⊖ EtOH
PMHx: sick sinus syndrome s/p pacemaker placmt, s/p CVA 1983, DJD, temporal arteritis

CTU 143823

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
- #1 Aspirin
- #2 Nabumetone 750mg tablet (Relafen)

2. Dose, frequency & route used
- #1 QD po
- #2 750mg BID po

Therapy dates (if unknown, give duration) from/to (or best estimate)
- #1
- #2

4. Diagnosis for use (indication)
- #1 CAD
- #2 ~~TC~~ DJD

5. Event abated after use stopped or dose reduced
- #1 ☐ yes ☒ no ☐ doesn't apply
- #2 ☐ yes ☒ no ☐ doesn't apply

6. Lot # (if known)
- #1
- #2

7. Exp. date (if known)
- #1
- #2

8. Event reappeared after reintroduction
- #1 ☐ yes ☐ no ☒ doesn't apply
- #2 ☐ yes ☐ no ☒ doesn't apply

9. NDC # (for product problems only)
- -
- -

10. Concomitant medical products and therapy dates (exclude treatment of event)

Prednisone 20mg 5x/day

D. Suspect medical device

1. Brand name

2. Type of device

3. Manufacturer name & address

RECEIVED
MAY 21 2001
MEDWATCH CTU

4. Operator of device
- ☐ health professional
- ☐ lay user/patient
- ☐ other:

5. Expiration date (mo/day/yr)

6.
- model #
- catalog #
- serial #
- lot #
- other #

7. If implanted, give date (mo/day/yr)

8. If explanted, give date (mo/day/yr)

9. Device available for evaluation? (Do not send to FDA)
☐ yes ☐ no ☐ returned to manufacturer on ___ (mo/day/yr)

10. Concomitant medical products and therapy dates (exclude treatment of event)

E. Reporter (see confidentiality section on back)

1. Name, address & phone #

[redacted] Health Center
[redacted] Dr.

2. Health professional? ☑ yes ☐ no

3. Occupation: Pharmacy Intern

4. Also reported to
- ☐ manufacturer
- ☐ user facility
- ☐ distributor

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box. ☒

Mail to: MEDWATCH, 5600 Fishers Lane, Rockville, MD 20852-9787
or FAX to: 1-800-FDA-0178

MAY 18 2001

FDA Form 3500 (5/99)

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

Individual Safety Report

3726404-8-00-01

Human Health Division

For use by user-facilities, listributors and manufacturers for MANDATORY reporting

Page 1

NO ATTACHMENT

50327623

Merck Facsimile of FDA Form 3500A
Approved by FDA (10/21/93)

Mfr report # WAES 01050285

UF/Dist report #

FDA Use Only

A. Patient information

1. Patient identifier	2. Age at time of event:	3. Sex	4. Weight
Unk	or 82 years	[X] Female	130 pounds
in confidence	Date of Birth: [redacted]	[ ] Male	

B. Adverse event or product problem

1. [X] Adverse event and / or [ ] Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

- [ ] death _____ (mo/day/yr)
- [ ] life-threatening
- [X] hospitalization-initial or prolonged
- [ ] disability
- [ ] congenital anomaly
- [ ] required intervention to prevent permanent impairment/damage
- [ ] other: _____

3. Date of event (mo/day/yr): 10/11/00

4. Date of this report (mo/day/yr): 05/16/01

5. Describe event or problem

This is in follow-up to report(s) previously submitted on 5/14/01

Information has been received for a report received from the FDA regarding an 82 year old female patient with hypertension and a history of myocardial infarction, percutaneous transluminal coronary angioplasty, coronary artery bypass graft and acute renal failure who, on 01-JAN-2000, was placed on therapy with rofecoxib, 12.5 mg, tablet, once a day (indication not reported). Concomitant therapy included aspirin, 325 mg, once daily, digoxin (LANOXIN), potassium chloride, clopidogrel bisulfate (PLAVIX), vitamins (unspecified) and isosorbide dinitrate (ISORDIL). In April 2000, the patient developed acute renal failure secondary to intravenous contrast (incidental finding). In April 2000, the patient's serum creatinine was 1.6 and blood urea nitrogen (BUN) 44. At that time, the patient's serum creatinine and BUN returned to "almost normal" (values not reported). On 11-OCT-2000, the patient developed melena and anemia, and experienced orthostasis. The patient was hospitalized.

(Continued on Additional Page)

6. Relevant tests/laboratory data, including dates

Refer to Additional Page

7. Other relevant history, including preexisting medical conditions (e.g., allergies,race,pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

MEDICAL HISTORY: acute renal failure; coronary bypass; myocardial infarction; percutaneous transluminal coronary angioplasty
CONCURRENT CONDITIONS: hypertension

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)

#1 TAB VIOXX 12.5 mg

#2 aspirin 325 mg

2. Dose, frequency & route used	3. Therapy dates (from/to) ; if unknown, give duration)
#1 12.5 mg/DAILY/PO	#1 01/01/00 - 10/11/00
#2 325 mg/DAILY/PO	#2 01/01/00 - 10/11/00

4. Diagnosis for use (indication)

#1 Unknown

#2 Unknown

5. Event abated after use stopped or dose reduced.

	yes	no	N/A	unk
#1	[X]	[ ]	[ ]	[ ]
#2	[ ]	[ ]	[ ]	[X]

6. Lot # (if known)

#1

#2

7. Exp date (if known)

#1

#2

8. Event reappeared after reintroduction.

	yes	no	N/A	unk
#1	[ ]	[ ]	[X]	[ ]
#2	[ ]	[ ]	[ ]	[X]

9. NDC # - for product problems only (if known)

Unknown

10. Concomitant medical products and therapy dates (exclude treatment of event)

ISORDIL Unk -Unk
LANOXIN Unk -Unk

(Continued on Additional Page)

G. All manufacturers

1. Contact office - name/address

Merck Human Health Division
Merck & Co., Inc.
P.O. Box 4
West Point, PA 19486-0004

ATTN: Worldwide Product Safety

2. Phone Number: (610)397-24[illegible]6

3. Report source (check all that apply)

- [ ] foreign
- [ ] study
- [ ] literature
- [ ] consumer
- [X] health professional
- [ ] user facility
- [ ] company representative
- [ ] distributor
- [X] other: CTU 140281

4. Date received by manufacturer (mo/day/yr): 05/10/01

5. NDA # 21042

IND #

PLA #

pre-1938 [ ] yes

OTC product [ ] yes

6. If IND, protocol #

7. Type of report

- [ ] 5-day
- [X] 15-day
- [ ] 10-day
- [ ] periodic
- [ ] initial
- [X] Follow-up# 1

9. Mfr report number: WAES 01050285

8. Adverse event term(s)

ACUTE RENAL FAILURE; ANEMIA; CARDIAC OUTPUT LOW; CARDIOMYOPATHY; EROSIVE GASTRITIS; DEHYDRATION; MELENA; ORTHOSTATIC SYMPTOMS

E. Initial reporter

1. Name, address & phone #

[redacted] AVENUE [redacted]

2. Health professional?	3. Occupation	4. Initial reporter also sent report to FDA.
[X] YES [ ] NO	R.Ph.	[ ] yes [ ] no [X] unk

FDA Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

B. Adverse ever

5. Describe event or problem

The patient's hemoglobin was "8.7%," hematocrit 27.1%, serum creatinine 3.6, and BUN 55. At that time rofecoxib and aspirin therapy were discontinued. A gastroscopy was performed which showed erosive, diffuse gastritis. The gastroenterology consult attributed the patient's melena, anemia, orthostasis, and gastritis to rofecoxib and aspirin. The patient was also again diagnosed with acute renal failure which was attributed by renal consult to decreased cardiac output (value not specified), volume depletion, ischemic cardiomyopathy, anemia and/or "NSAID" use. On 19-OCT-2000, the patient's serum creatinine was 1.7 and BUN 31. On 19-OCT-2000, the patient was released from the hospital. The report indicated that subsequently the patient's gastritis, melena, anemia, orthostasis, decreased cardiac output, volume depletion, ischemic cardiomyopathy, and acute renal failure subsided.

Follow up information has been received from the pharmacist who originally reported the information. The 82 year old female subsequently recovered from the diffuse gastritis, melena, anemia and orthostasis . Additional information is not expected.

This report was also received from the FDA through the Freedom of Information Act. There is no additional information.

This report was filed with the FDA. The CTU number is 140281 and the ISR number is 36925068.

6. Relevant tests/laboratory data, including dates

DIAGNOSTIC TEST

Tests	Date	Value	Unit	Normal Range
gastroscopy	10/??/00			
Comment: erosive, diffuse gastritis				

LABORATORY RESULTS

Tests	Date	Value	Unit	Normal Range
serum blood urea nitrogen	04/??/00	44		
serum blood urea nitrogen	04/??/00			
Comment: almost normal				
serum creatinine	04/??/00	1.6		
serum creatinine	04/??/00			
Comment: almost normal				
hematocrit	10/11/00	27.1	%	
hemoglobin	10/11/00	"8.7"	%	
serum blood urea nitrogen	10/11/00	55		
serum creatinine	10/11/00	3.6		
serum blood urea nitrogen	10/19/00	31		
serum creatinine	10/19/00	1.7		

C. Suspect medication(s)

10. Concomitant medical products and therapy dates (exclude treatment of event)

PLAVIX	Unk - Unk
potassium chloride	Unk - Unk
vitamins (unspecified)	Unk - Unk

Individual Safety Report

3729208-5-00-01

OLUNTARY reporting
th professionals of adverse
ts and product problems

Form Approved: OMB No. 0910-0291 Expires: 12/31/04
See OMB statement on reverse

FDA Use Only (MB)

Triage unit sequence # 144338

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM OP

Page ___ of ___

A. Patient information

1. Patient identifier	2. Age at time of event: / or Date of birth:	3. Sex	4. Weight
1115 In confidence	44	☒ female ☐ male	___ lbs or ___ kgs

B. Adverse event or product problem

1. ☒ Adverse event and/or ☐ Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)
- ☐ death ___ (mo/day/yr)
- ☐ life-threatening
- ☒ hospitalization – initial or prolonged
- ☐ disability
- ☐ congenital anomaly
- ☐ required intervention to prevent permanent impairment/damage
- ☐ other: ___

3. Date of event (mo/day/yr): 10/19/00

4. Date of this report (mo/day/yr):

5. Describe event or problem

coffee grounds emesis
abd. pain MEG
given PRBC

EGD showed 2 ulcers in duodenum.
NSAIDS + ASA were D/C'd.

6. Relevant tests/laboratory data, including dates

HCT 26 on admission
dropping to 22

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

CTV144338

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
- #1 Aspirin
- #2 Motrin PRN

2. Dose, frequency & route used
- #1 6 tabs daily
- #2 400mg X 1-2 t.i.d

3. Therapy dates (if unknown, give duration) (from/to (or best estimate))
- #1 → 10/19/00
- #2 → 10/19/00

4. Diagnosis for use (indication)
- #1 migraines
- #2 migraines

5. Event abated after use stopped or dose reduced
- #1 ☐ yes ☐ no ☐ doesn't apply
- #2 ☐ yes ☐ no ☐ doesn't apply

6. Lot # (if known)
- #1
- #2

7. Exp. date (if known)
- #1
- #2

8. Event reappeared after reintroduction
- #1 ☐ yes ☐ no ☐ doesn't apply
- #2 ☐ yes ☐ no ☐ doesn't apply

9. NDC # (for product problems only)
- –
- –

10. Concomitant medical products and therapy dates (exclude treatment of event)

D. Suspect medical device

1. Brand name

2. Type of device

3. Manufacturer name & address

RECEIVED
MAY 29 2001
MEDWATCH CTU

4. Operator of device
- ☐ health professional
- ☐ lay user/patient
- ☐ other: ___

5. Expiration date (mo/day/yr)

6.
- model # ___
- catalog # ___
- serial # ___
- lot # ___
- other # ___

7. If implanted, give date (mo/day/yr)

8. If explanted, give date (mo/day/yr)

9. Device available for evaluation? (Do not send to FDA)
☐ yes ☐ no ☐ returned to manufacturer on ___ (mo/day/yr)

10. Concomitant medical products and therapy dates (exclude treatment of event)

E. Reporter (see confidentiality section on back)

1. Name, address & phone #

VA HOSPITAL (119)
7400 MERTON MINTER BLVD.
SAN ANTONIO, TX 78284

2. Health professional? ☒ yes ☐ no

3. Occupation: Pharm D

4. Also reported to
- ☐ manufacturer
- ☐ user facility
- ☐ distributor

5. If you do NOT want your identity disclosed to the manufacturer, place an " X " in this box. ☒

FDA

Mail to: MEDWATCH
5600 Fishers Lane
Rockville, MD 20852-9787

or FAX to:
1-800-FDA-0178

...to an admission that medical personnel or the product caused or contributed to the event

Individual Safety Report

3729233-4-00-01

VOLUNTARY reporting
lth professionals of adverse
its and product problems

Form Approved: OMB No. 0910-0291 Expires: 12/31/94
See OMB statement on reverse

FDA Use Only (MB)

Triage unit sequence # 144354

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page ___ of ___

A. Patient information

1. Patient identifier	2. Age at time of event: / or Date of birth:	3. Sex	4. Weight
1125 In confidence	78	☐ female ☒ male	___ lbs or ___ kgs

B. Adverse event or product problem

1. ☑ Adverse event and/or ☐ Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)
- ☐ death ___ (mo/day/yr)
- ☐ life-threatening
- ☒ hospitalization – initial or prolonged
- ☐ disability
- ☐ congenital anomaly
- ☐ required intervention to prevent permanent impairment/damage
- ☐ other: ___

3. Date of event (mo/day/yr): 11/9/00

4. Date of this report (mo/day/yr)

5. Describe event or problem

Melena, ?hematemesis
Salicylate toxicity, MSchanges

SPEC SALICYL

	11/13/2000@03:45 SER	5.2
	11/11/2000@13:31 PLA	25.4
A	11/11/2000@04:38 SER	31.0 H*
B	11/10/2000@18:30 SER	38.3 H*
C	11/10/2000@10:45 SER	46.8 H*
D	11/10/2000@07:15 SER	49 H*
E	11/10/2000@05:00 SER	50.0 H*
F	11/10/2000@03:25 SER	53.3 H*
A	11/09/2000@18:50 SER	64.4 H*

CTV144354

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
#1 Aspirin
#2

2. Dose, frequency & route used
#1 large doses
#2

3. Therapy dates (if unknown, give duration) (from/to (or best estimate))
#1 → 11/9/00
#2

4. Diagnosis for use (indication)
#1
#2

5. Event abated after use stopped or dose reduced
#1 ☐ yes ☐ no ☐ doesn't apply
#2 ☐ yes ☐ no ☐ doesn't apply

6. Lot # (if known)
#1
#2

7. Exp. date (if known)
#1
#2

8. Event reappeared after reintroduction
#1 ☐ yes ☐ no ☐ doesn't apply
#2 ☐ yes ☐ no ☐ doesn't apply

9. NDC # (for product problems only)
- -

10. Concomitant medical products and therapy dates (exclude treatment of event)

D. Suspect medical device

1. Brand name

2. Type of device

3. Manufacturer name & address

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4. Operator of device
- ☐ health professional
- ☐ lay user/patient
- ☐ other: ___

5. Expiration date (mo/day/yr)

6.
model # ___
catalog # ___
serial # ___
lot # ___
other # ___

7. If implanted, give date (mo/day/yr)

8. If explanted, give date (mo/day/yr)

9. Device available for evaluation? (Do not send to FDA)
☐ yes ☐ no ☐ returned to manufacturer on ___ (mo/day/yr)

10. Concomitant medical products and therapy dates (exclude treatment of event)

E. Reporter (see confidentiality section on back)

1. Name, address & phone #
VA HOSPITAL (119)
7400 MERTON MINTER BLVD.
SAN ANTONIO, TX 78284

2. Health professional? ☒ yes ☐ no

3. Occupation: Pharm D

4. Also reported to
- ☐ manufacturer
- ☐ user facility
- ☐ distributor

5. If you do NOT want your identity disclosed to the manufacturer, place an " X " in this box. ☒

...dical personnel or the product caused or contributed to the even...

FDA

Mail to: MEDWATCH
5600 Fishers Lane
Rockville, MD 20852-9787

or FAX to:
1-800-FDA-0178

Individual Safety Report

3729433-3-00-01

: VOLUNTARY reporting
health professionals of adverse
vents and product problems

Page ___ of ___ 10

Form Approved: OMB No. 0910-0291 Expires:12/31/94
See OMB statement on reverse

FDA Use Only

Triage unit sequence # 144443

A. Patient information

1. Patient Identifier	2. Age at time of event: 70 or Date of birth:	3. Sex	4. Weight
[redacted] In confidence		☐ female ☑ male	154 lbs or ___ kgs

B. Adverse event or product problem

1. ☑ Adverse event and/or ☐ Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)
- ☐ death ___ (mo/day/yr)
- ☐ life-threatening
- ☑ hospitalization – initial or prolonged
- ☐ disability
- ☐ congenital anomaly
- ☐ required intervention to prevent permanent impairment/damage
- ☐ other: ___

3. Date of event (mo/day/yr): 11/16/00

4. Date of this report (mo/day/yr): 1/10/01

5. Describe event or problem

Patient presented to PCP follow-up appt, c/o feeling light-headed x 2 months. His BP had been dropping consistently. He admitted to weakness + 20lb weight loss in last 6 months. He had been taking an adult aspirin daily per the advice of his local M.D. He received 2 units of blood on admission. EGD reported from local M.D., showed an antral ulcer.

6. Relevant tests/laboratory data, including dates

Hct 31.0 (37-50) (11-16-00)
Hgb 10.2 (12-17)

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

HTN
emphysema
GERD
BPH
esophageal stricture

Significant smoking hx.
h/o alcohol abuse in past, but sober x 4 years.

CTV144443

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
#1 aspirin 325mg
#2

2. Dose, frequency & route used
#1 1 QD
#2

3. Therapy dates (if unknown, give duration) from to (or best estimate)
#1
#2

4. Diagnosis for use (indication)
#1 preventative therapy
#2

5. Event abated after use stopped or dose reduced
#1 ☐ yes ☐ no ☑ doesn't apply
#2 ☐ yes ☐ no ☐ doesn't apply

6. Lot # (if known)
#1
#2

7. Exp. date (if known)
#1
#2

8. Event reappeared after reintroduction
#1 ☐ yes ☐ no ☐ doesn't apply
#2 ☐ yes ☐ no ☐ doesn't apply

9. NDC # (for product problems only)
- -

10. Concomitant medical products and therapy dates (exclude treatment of event)

lansoprazole 30mg BID
nifedipine 90mg QD
terazosin 10mg QHS

D. Suspect medical device

1. Brand name

2. Type of device

3. Manufacturer name & address

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4. Operator of device
- ☐ health professional
- ☐ lay user/patient
- ☐ other: ___

5. Expiration date (mo/day/yr)

6.
model # ___
catalog # ___
serial # ___
lot # ___
other # ___

7. If implanted, give date (mo/day/yr)

8. If explanted, give date (mo/day/yr)

9. Device available for evaluation? (Do not send to FDA)
☐ yes ☐ no ☐ returned to manufacturer on ___ (mo/day/yr)

10. Concomitant medical products and therapy dates (exclude treatment of event)

E. Reporter (see confidentiality section on back)

1. Name, address & phone #
[redacted]
LAMC
1030 Jefferson Ave #119
Memphis, Tn 38104
[redacted]

2. Health professional? ☑ yes ☐ no

3. Occupation: Pharmacist

4. Also reported to
- ☐ manufacturer
- ☐ user facility
- ☐ distributor

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box. ☐

FDA

Mail to: MEDWATCH
5600 Fishers Lane
Rockville, MD 20852-9787

or FAX to:
1-800-FDA-0178

FDA Form 3500 (6/93)

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

Individual Safety Report

3729459-X-00-01

)LUNTARY reporting
h professionals of adverse
s and product problems

Form Approved: OMB No. 0910-0291 Expires:12/31/94
See OMB statement on reverse

FDA Use Only

Triage unit sequence # 144394

HE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page ___ of ___

A. Patient information

1. Patient identifier: [redacted]5504 In confidence
2. Age at time of event: ___ or Date of birth: [redacted]
3. Sex: ☐ female ☑ male
4. Weight: ___ lbs or ___ kgs

B. Adverse event or product problem

1. ☑ Adverse event and/or ☐ Product problem (e.g., defects/malfunctions)
2. Outcomes attributed to adverse event (check all that apply)
   - ☐ death ___ (mo/day/yr)
   - ☑ life-threatening
   - ☑ hospitalization – initial or prolonged
   - ☐ disability
   - ☐ congenital anomaly
   - ☑ required intervention to prevent permanent impairment/damage
   - ☐ other: ___
3. Date of event (mo/day/yr): 3/16/01
4. Date of this report (mo/day/yr): 5/14/01
5. Describe event or problem

81 YOAAM adm for OSH for prolonged CP s/p AAA repair on 2/19. Complicated hospital course. On 3/16, blood in stool and Hgb decrease from 10.2 to 5.5 in 24 hrs. ASA D/C'd. Endoscopy revealed erosions on duodenal bulb and lower stomach. Pt. transferred to MICU. H.Pylori neg. On 3/18, Hgb again decreased from 12.1 to 8.2. Pt. had received daily ASA for a month before bleeding first noted. Likely cause felt to be NSAID in combination with other stressors. Hgb stable around 10 as of 3/22.

Relevant tests/laboratory data, including dates

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Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

NKDA
PMH: AAA, CRI, COPD, GERD, G6PD

CTU 144394

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
   #1 Aspirin
   #2
2. Dose, frequency & route used
   #1 325 mg PO qd
   #2
3. Therapy dates (if unknown, give duration) from/to (or best estimate)
   #1 2/14-3/18/01
   #2
4. Diagnosis for use (indication)
   #1 prophylaxis, MI
   #2
5. Event abated after use stopped or dose reduced
   #1 ☐ yes ☐ no ☑ doesn't apply
   #2 ☐ yes ☐ no ☐ doesn't apply
6. Lot # (if known)
   #1
   #2
7. Exp. date (if known)
   #1
   #2
8. Event reappeared after reintroduction
   #1 ☐ yes ☐ no ☐ doesn't apply
   #2 ☐ yes ☐ no ☐ doesn't apply
9. NDC # (for product problems only)
   - -
10. Concomitant medical products and therapy dates (exclude treatment of event)
albuterol docusate MOM
amio FeSO4 omeprazole
ascorbic acid ipatropium prednisone
diltiazem levoflox

D. Suspect medical device

1. Brand name
2. Type of device
3. Manufacturer name & address
4. Operator of device
   - ☐ health professional
   - ☐ lay user/patient
   - ☐ other: ___
5. Expiration date (mo/day/yr)
6. model # ___
   catalog # ___
   serial # ___
   lot # ___
   other # ___
7. If implanted, give date (mo/day/yr)
8. If explanted, give date (mo/day/yr)
9. Device available for evaluation? (Do not send to FDA)
   ☐ yes ☐ no ☐ returned to manufacturer on ___ (mo/day/yr)
10. Concomitant medical products and therapy dates (exclude treatment of event)

E. Reporter (see confidentiality section on back)

1. Name, address & phone #
   [redacted], PharmD
   Hospital [redacted]
   Department of Pharmacy Services
   [redacted] Street - [redacted]
   [redacted]
   Phone: [redacted]
2. Health professional? ■ yes ☐ no
3. Occupation: Pharmacist
4. Also reported to
   - ☐ manufacturer
   - ■ user facility
   - ☐ distributor
5. If you do NOT want your identity disclosed to the manufacturer, place an " X " in this box. ■

DA

Mail to: MEDWATCH, 5600 Fishers Lane, Rockville, MD 20852-9787 or FAX to: 1-800-FDA-0178

Individual Safety Report

3729488-6-00-01

)LUNTARY reporting
h professionals of adverse
s and product problems

Form Approved: OMB No. 0910-0291 Expires:12/31/94
See OMB statement on reverse

FDA Use Only

Triage unit sequence # 144410

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page ___ of ___ CONT'D

A. Patient information

1. Patient identifier	2. Age at time of event: / or Date of birth:	3. Sex	4. Weight
5495-[redacted] In confidence	75	☐ female ☐ male	___ lbs or ___ kgs

B. Adverse event or product problem

1. ☑ Adverse event and/or ☐ Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)
- ☐ death ___ (mo/day/yr)
- ☑ life-threatening
- ☑ hospitalization – initial or prolonged
- ☐ disability
- ☐ congenital anomaly
- ☑ required intervention to prevent permanent impairment/damage
- ☐ other: ___

3. Date of event (mo/day/yr)	4. Date of this report (mo/day/yr)
4/9/01	5/14/01

5. Describe event or problem

75 YOM found at home in pool of blood with aspirin. Pt brought to OSH ER on 4/9 with INR=11.7, Hgb=8.9. Gastric lavage was (+) for blood. EGD on 4/10 revealed an arterial vessel lesion of the duodenal bulb supposedly secondary to aspirin. Pt also on warfarin 2.5mg/5mg po QD alternating. Warfarin most likely exacerbated the situation. Pt transferred from OSH since ICU beds full. Pt received 4 units of PRBCs and FFP on 4/9-4/10. (+) melena. Upon transfer, Hgb=6.1. On 4/13, Hgb=9.1

6. Relevant tests/laboratory data, including dates

	4/9	4/10	4/11	4/12	4/13
Hgb	6.1	8.1	9.8	9.5	9.1

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Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

NKDA
PMH: Afib, HTN, TIA, arthritis, Bladder atony, Urosepsis

CTU 144410

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
- #1 ASA
- #2 Warfarin

2. Dose, frequency & route used	3. Therapy dates (if unknown, give duration) from/to (or best estimate)
#1 85 mg	#1 3/31-4/9/01
#2 2.5/5 mg alt.	#2 3/31-4/9/01

4. Diagnosis for use (indication)	5. Event abated after use stopped or dose reduced
#1 Afib	#1 ☐ yes ☐ no ☑ doesn't apply
#2 Afib	#2 ☐ yes ☐ no ☑ doesn't apply

6. Lot # (if known)	7. Exp. date (if known)
#1	#1
#2	#2

8. Event reappeared after reintroduction
- #1 ☐ yes ☐ no ☐ doesn't apply
- #2 ☐ yes ☐ no ☐ doesn't apply

9. NDC # (for product problems only) - -

10. Concomitant medical products and therapy dates (exclude treatment of event)

Metoprolol	captopril
ranitidine	amoxicillin/clavulanate
amiodarone	warfarin

D. Suspect medical device

1. Brand name

2. Type of device

3. Manufacturer name & address

4. Operator of device
- ☐ health professional
- ☐ lay user/patient
- ☐ other: ___

6. model # ___
catalog # ___
serial # ___
lot # ___
other # ___

5. Expiration date (mo/day/yr)

7. If implanted, give date (mo/day/yr)

8. If explanted, give date (mo/day/yr)

9. Device available for evaluation? (Do not send to FDA)
☐ yes ☐ no ☐ returned to manufacturer on ___ (mo/day/yr)

10. Concomitant medical products and therapy dates (exclude treatment of event)

E. Reporter (see confidentiality section on back)

1. Name, address & phone #
[redacted], PharmD
Hospital [redacted]
Department of Pharmacy Services
[redacted] Street - [redacted]
Phone: [redacted]

2. Health professional?	3. Occupation	4. Also reported to
■ yes ☐ no	Pharmacist	☐ manufacturer ■ user facility ☐ distributor

5. If you do NOT want your identity disclosed to the manufacturer, place an " X " in this box. ■

Mail to: MEDWATCH, 5600 Fishers Lane, Rockville, MD 20852-9787 or FAX to: 1-800-FDA-0178

Form 3500 (6/93) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

Individual Safety Report

3729622-8-00-01

MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

for VOLUNTARY reporting by health professionals of adverse events and product problems

Form Approved: OMB No. 0910-0291 Expires: 12/31/98
See OMB Statement on reverse.

FDA Use Only (Intended)

Triage unit sequence # 144482

A. Patient information

1. Patient identifier	2. Age at time of event: or Date of birth:	3. Sex	4. Weight
XX In confidence	33 yr	☐ female ☑ male	____ lbs or ____ kgs

B. Adverse event or product problem

1. ☑ Adverse event and/or ☐ Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

☐ death ____ (mo/da/yr)
☐ life-threatening
☑ hospitalization – initial or prolonged
☐ disability
☐ congenital anomaly
☐ required intervention to prevent permanent impairment/damage
☐ other: ____

3. Date of event (mo/da/yr)	4. Date of this report (mo/da/yr)
2-10-01	5-29-01

5. Describe event or problem

GASTROINTESTINAL BLEED: MELENA. Patient taking Aspirin & Ibuprofen for epigastric pain had 1 episode of melena & felt dizzy. Came to hospital where H/H stable at 10.6/31.6; EGD showed multiple linear erosion in antrum & 1cm clean based ulcer in duodenal bulb. Final DG: NSAID induced gastric ulcers. To be F/U in clinic.

6. Relevant tests/laboratory data, including dates

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

CTV144480

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
#1 ASPIRIN
#2 IBUPROFEN

2. Dose, frequency & route used
#1
#2

3. Therapy dates (if unknown, give duration)
#1
#2

4. Diagnosis for use (indication)
#1
#2

5. Event abated after use stopped or dose reduced
#1 ☐ yes ☐ no ☐ doesn't apply
#2 ☐ yes ☐ no ☐ doesn't apply

6. Lot # (if known)
#1
#2

7. Exp. date (if known)
#1
#2

8. Event reappeared after reintroduction
#1 ☐ yes ☐ no ☐ doesn't apply
#2 ☐ yes ☐ no ☐ doesn't apply

9. NDC # (for product problems only)
– –

10. Concomitant medical products and therapy dates (exclude treatment of event)

D. Suspect medical device

1. Brand name

2. Type of device

3. Manufacturer name & address

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4. Operator of device
☐ health professional
☐ lay user/patient
☐ other: ____

6. model # MEDWATCH CTU
catalog #
serial #
lot #
other #

5. Expiration date (mo/da/yr)

7. If implanted, give date (mo/da/yr)

8. If explanted, give date (mo/da/yr)

9. Device available for evaluation? (Do not send to FDA)
☐ yes ☐ no ☐ returned to manufacturer on ____ (mo/da/yr)

10. Concomitant medical products and therapy dates (exclude treatment of event)

E. Reporter (see confidentiality section on back)

1. Name, address & phone #
[redacted] DSS
[redacted] MED CTR Rm [redacted]
[redacted] ST
MAY 30 2001

2. Health professional?	3. Occupation	4. Also reported to
☑ yes ☐ no	PHARMACIST	☐ manufacturer ☐ user facility ☐ distributor

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box. ☒

Mail to: MEDWATCH, 5600 Fishers Lane, Rockville, MD 20852-9787
or FAX to: 1-800-FDA-0178

FDA Form 3500 (6/93)

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

MAY 29 2001

SENT BY: 5-29- 1 ; 9:43AM ; LACTUSC DRUG INFO → 18003320178:#11/19

Individual Safety Report

3729648-4-00-01

MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

For VOLUNTARY reporting by health professionals of adverse events and product problems

Page 1 of 1

Form Approved: OMB No. 0910-0291 Expires: 12/31/98
See OMB statement on reverse

FDA Use Only (Intertrak)

Triage unit sequence # 144489

A. Patient information

1. Patient identifier	2. Age at time of event: or Date of birth:	3. Sex	4. Weight
XX (in confidence)	51yr	☐ female ☑ male	____ lbs or ____ kgs

B. Adverse event or product problem

1. ☑ Adverse event and/or ☐ Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

- ☐ death (mm/dd/yy)
- ☐ life-threatening
- ☑ hospitalization – initial or prolonged
- ☐ disability
- ☐ congenital anomaly
- ☐ required intervention to prevent permanent impairment/damage
- ☐ other:

3. Date of event (mm/dd/yy): 2-14-01

4. Date of this report (mm/dd/yy): 5-29-01

5. Describe event or problem

GI BLEED: HEMATEMESIS & HEMATOCHEZIA. Patient taking Aspirin BID to QID x 1 year b/o headache came to hospital c/o BRB mixed w/ stool x 5 over the last 5 hours, c/o dizzy while standing. Also vomited blood x 2 on day prior to coming to hospital. Hbg in ER about 9. EGD showed antral ulcer w/ small vessel base. Treatment: BICAPed & injected. Patient's H/H remained stable. Final DG: Gastric Ulcer d/t NSAID.

6. Relevant tests/laboratory data, including dates

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

CTV144489

C. Suspect medication(s)

1. Name (give labeled strength & manufacturer, if known)
#1 Aspirin
#2

2. Dose, frequency & route used
#1
#2

3. Therapy dates (if unknown, give duration) (mm/dd/yy or best estimate)
#1
#2

4. Diagnosis for use (indication)
#1
#2

5. Event abated after use stopped or dose reduced
#1 ☐ yes ☐ no ☐ doesn't apply
#2 ☐ yes ☐ no ☐ doesn't apply

6. Lot # (if known)
#1
#2

7. Exp. date (if known)
#1
#2

8. Event reappeared after reintroduction
#1 ☐ yes ☐ no ☐ doesn't apply
#2 ☐ yes ☐ no ☐ doesn't apply

9. NDC # (for product problems only)
– –

10. Concomitant medical products and therapy dates (exclude treatment of event)

D. Suspect medical device

1. Brand name

2. Type of device

3. Manufacturer name & address

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MEDWATCH CTU

4. Operator of device
☐ health professional
☐ lay user/patient
☐ other:

5. Expiration date (mm/dd/yy)

6. model #
catalog #
serial #
lot #
other #

7. If implanted, give date (mm/dd/yy)

8. If explanted, give date (mm/dd/yy)

9. Device available for evaluation? (Do not send to FDA)
☐ yes ☐ no ☐ returned to manufacturer on (mm/dd/yy)

10. Concomitant medical products and therapy dates (exclude treatment of event)

E. Reporter (see confidentiality section on back)

1. Name, address & phone #
[redacted] DSS
[redacted] MED CTR
[redacted] ST Rm [redacted]
MAY 30 2001

2. Health professional? ☑ yes ☐ no

3. Occupation: PHARMACIST

4. Also reported to
☐ manufacturer
☐ user facility
☐ distributor

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box. ☒

Mail to: MEDWATCH, 5600 Fishers Lane, Rockville, MD 20852-9787 or FAX to: 1-800-FDA-0178

FDA Form 3500 (6/93)

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

MAY 29 2001

SENT BY: 5-29- 1 ; 9:40AM ; LACTUSC DRUG INFO → 18003320178:# 2/19

Approved by FDA on 3-22-94

Individual Safety Report

3729856-2-00-01

ME

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

ıthelabo Inc.

Page 1 of 2

Domain Facsimile

Mfr report # T200100274

UF/Dist report #

FDA Use Only

A. Patient information

patient identifier	2. Age at time of event:	3. Sex	4. Weight
[redacted] in confidence	62 yrs or ____ Date of birth: [redacted]	☐ female ☒ male	____ lbs or 94.5 kgs

B. Adverse event or product problem

1. ☒ Adverse event and/or ☐ Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)
- ☒ death 10/17/2001 (mo/day/yr)
- ☐ life-threatening
- ☒ hospitalization - initial or prolonged
- ☐ disability
- ☐ congenital anomaly
- ☐ required intervention to prevent permanent impairment/damage
- ☐ other: ____

3. Date of event (mo/day/yr): 09/17/1999

4. Date of this report (mo/day/yr): 05/22/2001

5. Describe event or problem

The following report was received from the unsponsored VA-CSP 440 trial "Antithrombotic Agents in the Prevention of Hemodialysis Access Thrombosis," a study from the Veterans Affairs Cooperative Studies Program (conducted under a VA IND). Sanofi-Synthelabo Inc. initially reported a summary of this trial in Manufacturer Case ID 1999USA01454. The blind was broken, and on 11 May 2001, Sanofi-Synthelabo Inc. received the case reports from those patients who experienced adverse events while being treated with the clopidogrel/aspirin combination.

Patient 549-04 / Initials [redacted] Visit Two: A 62-year-old male treated with Plavix (clopidogrel) and aspirin experienced CAD *

6. Relevant tests/laboratory data, including dates

NI

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

Four years since last smoked.
Concomitant disease(s): Congestive heart failure, Hypertension

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
- #1 PLAVIX
- #2 Aspirin

2. Dose, frequency & route used
- #1 75 mg QD PO
- #2 325 mg QD PO

3. Therapy dates (if unknown, give duration) from/to (or best estimate)
- #1 NI to NI
- #2 NI to NI

4. Diagnosis for use (indication)
- #1 *
- #2 *

5. Event abated after use stopped or dose reduced
- #1 ☐ yes ☐ no ☐ doesn't appl
- #2 ☐ yes ☐ no ☐ doesn't appl

6. Lot # (if known)
- #1 NI
- #2 NI

7. Exp. date (if known)
- #1 NI
- #2 NI

8. Event reappeared after reintroduction
- #1 ☐ yes ☐ no ☐ doesn't appl
- #2 ☐ yes ☐ no ☐ doesn't appl

9. NDC # - for product problems only (if known)
- #1 NI
- #2 NI

10. Concomitant medical products and therapy dates (exclude treatment of event)

Name: EPOGEN Dates:
Name: Fosinopril Dates:
Name: Folic acid Dates: *

G. All manufacturers

1. Contact office - name/address (& mfring site for devices)

Sanofi-Synthelabo Inc.
90 Park Avenue
New York, NY 10016

2. Phone number: (212) 551-4000

3. Report source (check all that apply)
- ☐ foreign
- ☒ study
- ☐ literature
- ☐ consumer
- ☒ health professional
- ☐ user facility
- ☐ company representative
- ☐ distributor
- ☐ other:

4. Date received by manufacturer (mo/day/yr): 05/11/2001

5. (A)NDA # 20-839
- IND # ____
- PLA # ____
- pre-1938 ☐ yes
- OTC product ☐ yes

6. If IND, protocol #

7. Type of report (check all that apply)
- ☐ 5-day ☒ 15-day
- ☐ 10-day ☐ periodic
- ☒ Initial ☐ follow-up #____

8. Adverse event term(s)

CORONARY ARTERY DISORDER, UNCODED EVENT, SEPSIS, CARDIAC ARREST, DUODENAL ULCER

9. Mfr. report number: T200100274

E. Initial reporter

1. Name, address & phone #

[redacted]
Boston University School of Medicine
Boston VA Medical Center
150 South Huntington Ave *

2. Health professional? ☒ yes ☐ no

3. Occupation: STUDY CHAIRMAN

4. Initial reporter also sent report to FDA ☐ yes ☐ no ☐ unk

FDA

Domain Facsimile of FDA Form 3500A

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

Item completed on continuation pages.

B.5. Describe event or problem

[continuation:] on 17 Sept 1999, kidney transplant (date unspecified), sepsis, and cardiac arrest on 17 Oct 1999. Randomization date was 11 January 1999. Descriptions of event read: "ESRD on dialysis" and "GI bleeding requiring transfusion, surgery involving cardiac arrest. Sepsis." Patient was hospitalized on 29 Sept 1999, and died on 17 Oct 1999. Primary reason: duodenal ulcer, hemorrhage. Secondary reason: septic shock.

Assessment of relationship to study drug by Investigator: Possible
Same patient as T200100273.
Corrective treatment: transfusion, surgery.

C.4. Diagnosis for use (indication) (Suspect #1)

prevention of hemodialysis access thrombosis

C.4. Diagnosis for use (indication) (Suspect #2)

prevention of hemodialysis access thrombosis

C.10. Concomitant medical products and therapy dates (exclude treatment of event)

[continuation:] Name: MULTIVITAMINS Dates:
Name: Iron IV Dates: NI to NI
Name: TUMS Dates:
Name: PHOSLO Dates:

Name, address & phone #

[continuation:]
[redacted] UNITED STATES

Individual Safety Report

3729857-4-00-01

MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Synthelabo Inc.

Approved by FDA on 12/22/94

Domain Facsimile

Mfr report # T200100270

UF/Dist report #

FDA Use Only

A. Patient information

Patient identifier	2. Age at time of event:	3. Sex	4. Weight
[redacted] in confidence	59 yrs or Date of birth: [redacted]	☐ female ☒ male	NI lbs or NI kgs

B. Adverse event or product problem

1. ☒ Adverse event and/or ☐ Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)
- ☐ death (mo/day/yr)
- ☐ life-threatening
- ☒ hospitalization - initial or prolonged
- ☐ disability
- ☐ congenital anomaly
- ☐ required intervention to prevent permanent impairment/damage
- ☐ other:

3. Date of event (mo/day/yr): 03/30/1999

4. Date of this report (mo/day/yr): 05/22/2001

5. Describe event or problem

The following report was received from the unsponsored VA-CSP 440 trial "Antithrombotic Agents in the Prevention of Hemodialysis Access Thrombosis," a study from the Veterans Affairs Cooperative Studies Program (conducted under a VA IND). Sanofi-Synthelabo Inc. initially reported a summary of this trial in Manufacturer Case ID 1999USA01454. The blind was broken, and on 11 May 2001, Sanofi-Synthelabo Inc. received the case reports from those patients who experienced adverse events while being treated with the clopidogrel/aspirin combination.

Patient 541-05 / Initials: [redacted]

A 59-year-old male, who began Plavix *

6. Relevant tests/laboratory data, including dates

30 March 1999: Hematocrit: 15.9

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

previous history of GI bleed in March 1998
Concomitant disease(s): Not reported

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
- #1 PLAVIX
- #2 Aspirin

2. Dose, frequency & route used
- #1 75 mg QD PO
- #2 325 mg QD PO

3. Therapy dates (from/to (or best estimate))
- #1 12-FEB-1999 to 30-MAR-1999
- #2 12-FEB-1999 to 30-MAR-1999

4. Diagnosis for use (indication)
- #1 *
- #2 *

5. Event abated after use stopped or dose reduced
- #1 ☐ yes ☐ no ☐ doesn't apply
- #2 ☐ yes ☐ no ☐ doesn't apply

6. Lot # (if known)
- #1 NI
- #2 NI

7. Exp. date (if known)
- #1 NI
- #2 NI

8. Event reappeared after reintroduction
- #1 ☐ yes ☐ no ☐ doesn't apply
- #2 ☐ yes ☐ no ☐ doesn't apply

9. NDC # - for product problems only (if known)
- #1 NI
- #2 NI

10. Concomitant medical products and therapy dates (exclude treatment of event)

Name: Lansoprazole Dates:
Name: MINIMS ARTIFICIAL TEARS Dates:
Name: NEPHROCAPS Dates: *

G. All manufacturers

1. Contact office - name/address (& mfring site for devices)

Sanofi-Synthelabo Inc.
90 Park Avenue
New York, NY 10016

2. Phone number: (212) 551-4000

3. Report source (check all that apply)
- ☐ foreign
- ☒ study
- ☐ literature
- ☐ consumer
- ☒ health professional
- ☐ user facility
- ☐ company representative
- ☐ distributor
- ☐ other:

4. Date received by manufacturer (mo/day/yr): 05/11/2001

5. (A)NDA # 20-839
- IND #
- PLA #
- pre-1938 ☐ yes
- OTC product ☐ yes

6. If IND, protocol #

7. Type of report (check all that apply)
- ☐ 5-day ☒ 15-day
- ☐ 10-day ☐ periodic
- ☒ Initial ☐ follow-up #

8. Adverse event term(s)

GI HAEMORRHAGE, ANAEMIA

9. Mfr. report number

T200100270

E. Initial reporter

1. Name, address & phone #

[redacted]
Boston University School of Medicine
Boston VA Medical Center
150 South Huntington Ave.*

2. Health professional? ☒ yes ☐ no

3. Occupation: STUDY CHAIRMAN

4. Initial reporter also sent report to FDA ☐ yes ☐ no ☐ unk

FDA

Domain Facsimile of FDA Form 3500A

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

Item completed on continuation pages.

B.5. Describe event or problem

[continuation:] (clopidogrel)# and aspirin on 12 February 1999, experienced a hematocrit of 15.9 and GI bleed on 30 March 1999. Patient noticed blood in stool on 30 March 1999. Hematocrit was 15.9 on that same day. Patient's hematocrit had been continually decreasing since initiation of study drug on 12 February 1999. No further information is available.

Outcome: Recovered
Assessment of relationship to study drug by Investigator: Possible
Corrective treatment: Not reported

C.4. Diagnosis for use (indication) (Suspect #1)

prevention of hemodialysis access thrombosis

C.4. Diagnosis for use (indication) (Suspect #2)

prevention of hemodialysis access thrombosis

C.10. Concomitant medical products and therapy dates (exclude treatment of event)

[continuation:] Name: Iron Dates:

E.1. Name, address & phone #

[continuation:]

[redacted] UNITED STATES

Individual Safety Report

3729859-8-00-01

MI

FDA MEDICAL PRODUCTS REPORTING PROGRAM

nthelabo Inc.

Approved by FDA on 3/22/94

Domain Facsimile

Mfr report # T200100268

UF/Dist report #

FDA Use Only

A. Patient information

Patient identifier	2. Age at time of event:	3. Sex	4. Weight
[redacted] in confidence	78 yrs or Date of birth: [redacted]	☐ female ☒ male	NI lbs or NI kgs

B. Adverse event or product problem

1. ☒ Adverse event and/or ☐ Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)
- ☐ death ____ (mo/day/yr)
- ☐ life-threatening
- ☒ hospitalization - initial or prolonged
- ☐ disability
- ☐ congenital anomaly
- ☐ required intervention to prevent permanent impairment/damage
- ☐ other: ____

3. Date of event (mo/day/yr)	4. Date of this report (mo/day/yr)
05/26/1999	05/22/2001

5. Describe event or problem

The following report was received from the unsponsored VA-CSP 440 trial "Antithrombotic Agents in the Prevention of Hemodialysis Access Thrombosis," a study from the Veterans Affairs Cooperative Studies Program (conducted under a VA IND). Sanofi-Synthelabo Inc. initially reported a summary of this trial in Manufacturer Case ID 1999USA01454. The blind was broken, and on 11 May 2001, Sanofi-Synthelabo Inc. received the case reports from those patients who experienced adverse events while being treated with the clopidogrel/aspirin combination.

Patient 689-02 / Initials [redacted]: A 78-year-old male received Plavix (clopidogrel) and aspirin, and experienced gastric ulcer *

6. Relevant tests/laboratory data, including dates

NI

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

No prior history of GI bleed. Had hypotension upon preservation but responded to volume replacement. Taking Cimetadine prophylactically prior to event. Concomitant disease(s): Congestive heart failure, myocardial infarction, angina, *

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
- #1 PLAVIX
- #2 Aspirin

2. Dose, frequency & route used	3. Therapy dates (if unknown, give duration) from/to (or best estimate)
#1 75 mg QD PO	#1 NI to NI
#2 325 mg QD PO	#2 NI to NI

4. Diagnosis for use (indication)
- #1 *
- #2 *

5. Event abated after use stopped or dose reduced
- #1 ☐ yes ☐ no ☐ doesn't apply
- #2 ☐ yes ☐ no ☐ doesn't apply

6. Lot # (if known)	7. Exp. date (if known)
#1 NI	#1 NI
#2 NI	#2 NI

8. Event reappeared after reintroduction
- #1 ☐ yes ☐ no ☐ doesn't apply
- #2 ☐ yes ☐ no ☐ doesn't apply

9. NDC # - for product problems only (if known)
- #1 NI
- #2 NI

10. Concomitant medical products and therapy dates (exclude treatment of event)

Name: Metoprolol Dates:
Name: Allopurinol Dates:
Name: Calcitriol Dates: *

G. All manufacturers

1. Contact office - name/address (& mfring site for devices)

Sanofi-Synthelabo Inc.
90 Park Avenue
New York, NY 10016

2. Phone number: (212) 551-4000

3. Report source (check all that apply)
- ☐ foreign
- ☒ study
- ☐ literature
- ☐ consumer
- ☒ health professional
- ☐ user facility
- ☐ company representative
- ☐ distributor
- ☐ other:

4. Date received by manufacturer (mo/day/yr): 05/11/2001

5. (A)NDA # 20-839
- IND # ____
- PLA # ____
- pre-1938 ☐ yes
- OTC product ☐ yes

6. If IND, protocol #

7. Type of report (check all that apply)
- ☐ 5-day ☒ 15-day
- ☐ 10-day ☐ periodic
- ☒ Initial ☐ follow-up #____

8. Adverse event term(s)

GASTRIC ULCER HAEMORRHAGIC, GI HAEMORRHAGE

9. Mfr. report number: T200100268

E. Initial reporter

1. Name, address & phone #

[redacted]
Boston University School of Medicine
Boston VA Medical Center
150 South Huntington Ave *
MA [redacted]

2. Health professional?	3. Occupation	4. Initial reporter also sent report to FDA
☒ yes ☐ no	STUDY CHAIRMAN	☐ yes ☐ no ☐ unk

FDA

Domain Facsimile of FDA Form 3500A

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

* Item completed on continuation pages.

B.5. Describe event or problem

[continuation:] hemorrhage and upper GI bleed on 26 May 1999. Randomization date was 24 April 1999. Description: He had awoke with vague abdominal discomfort, and vomited blood at 5:45 am. Came to Emergency Room at 7:00 am. Surgery date for gastroectomy was 31 May 1999. Patient was discharged 02 July 1999.

Outcome: Recovered 31 May 1999.
Relationship to study drug: Definite
Corrective treatment: Cimetadine and DDAVP; gastrectomy.

B.7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

[continuation:] hypertension

C.4. Diagnosis for use (indication) (Suspect #1)

prevention of hemodialysis access thrombosis

C.4. Diagnosis for use (indication) (Suspect #2)

prevention of hemodialysis access thrombosis

C.10. Concomitant medical products and therapy dates (exclude treatment of event)

[continuation:] Name: Calcium acetate Dates:
Name: Folic acid Dates:

E.1. Name, address & phone #

[continuation:]
[redacted] UNITED STATES

Individual Safety Report

3733724-X-00-01

)LUNTARY reporting
h professionals of adverse
s and product problems

Form Approved: OMB No. 09[illegible]0291 Expires: 0[illegible]/2003
See OMB statement on reverse

FDA Use Only
Triage unit sequence # 144796

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Internet Submission - Page 1

A. Patient information

1. Patient Identifier	2. Age at time of event: or Date of birth:	3. Sex	4. Weight
025947 In confidence	[redacted]	☐ female ☑ male	235 lbs or ____ kgs

B. Adverse event or product problem

1. ☑ Adverse event and/or ☐ Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)
- ☐ death ____ (mm/dd/yyyy)
- ☑ life-threatening
- ☐ hospitalization – initial or prolonged
- ☐ disability
- ☐ congenital anomaly
- ☐ required intervention to prevent permanent impairment/damage
- ☐ other: ____

3. Date of event (mm/dd/yyyy): 05/30/2001

4. Date of this report (mm/dd/yyyy): 06/04/2001

5. Describe event or problem

Patient receiving Lovenox and ASA developed a GI bleed which required transfusions of blood

DSS

JUN 0 6 2001

6. Relevant tests/laboratory data, including dates

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

JUN - 4 2001

CTV144796

C. Suspect medication(s)

1. Name (Product Name)	(Labeled Strength)	(Mfr/Labeler)
#1 Lovenox	100mg	
#2 Aspirin	325mg	

2. Dose/Frequency/Route used			3. Therapy dates (if unknown, give duration) From	To (or best estimate)
#1 105mg	bid	Subcutaneous	#1 05/23/2001	05/30/2001
#2 325	qd	Oral	#2 05/23/2001	05/30/2001

4. Diagnosis for use (separate indications with commas)
#1 anti platelet
#2 anti platelet

5. Event abated after use stopped or dose reduced
#1 ☑ yes ☐ no ☐ doesn't apply
#2 ☑ yes ☐ no ☐ doesn't apply

6. Lot # (if known) #1 ____ #2 ____

7. Exp. date (if known) #1 ____ #2 ____

8. Event reappeared after reintroduction
#1 ☐ yes ☐ no ☐ doesn't apply
#2 ☐ yes ☐ no ☐ doesn't apply

9. NDC # (for product problems only) - -

10. Concomitant medical products and therapy dates (exclude treatment of event)

D. Suspect medical device

1. Brand name

2. Type of device

3. Manufacturer name & address

RECEIVED
JUN 0 5 2001

4. Operator of device
- ☐ health professional
- ☐ lay user/patient
- ☐ other: ____

6. model # MEDWATCH CTU
catalog # ____
serial # ____
lot # ____
other # ____

5. Expiration date (mm/dd/yyyy)

7. If implanted, give date (mm/dd/yyyy)

8. If explanted, give date (mm/dd/yyyy)

9. Device available for evaluation? (Do not send device to FDA)
☐ yes ☐ no ☐ returned to manufacturer on ____ (mm/dd/yyyy)

10. Concomitant medical products and therapy dates (exclude treatment of event)

E. Reporter (see confidentiality section on back)

1. Name [redacted] phone # [redacted]

[redacted] Medical Center Pharmacy, [redacted]
[redacted] Rd
[redacted]
United States

2. Health professional? ☑ yes ☐ no

3. Occupation: Pharmacist

4. Also reported to
- ☐ manufacturer
- ☐ user facility
- ☐ distributor

5. If you do not want your identity disclosed to the manufacturer, place an "X" in this box. ☑

FDA

Mail to: MEDWATCH
5600 Fishers Lane
Rockville, MD 20852-9787

or FAX to:
1-800-FDA-0178

FDA Form 3500

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

Individual Safety Report

3735655-8-00-01

145004

MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

For use by user-facilities, distributors and manufacturers for MANDATORY reporting

Page 1 of 1

Form Approved: OMB No. 1910-0291 Expires: 04/30/03
See OMB statement on reverse

Mfr report #

FDA Use Only

PLEASE TYPE OR USE BLACK INK

A. Patient information

1. Patient identifier: In confidence
2. Age at time of event: or Date of birth: [redacted]
3. Sex: ☐ female ☑ male
4. Weight: ____ lbs or 66 kgs

B. Adverse event or product problem

1. ☑ Adverse event and/or ☐ Product problem (e.g., defects/malfunctions)
2. Outcomes attributed to adverse event (check all that apply)
   - ☐ death ____ (mo/day/yr)
   - ☐ life-threatening
   - ☒ hospitalization – initial or prolonged
   - ☐ disability
   - ☐ congenital anomaly
   - ☐ required intervention to prevent permanent impairment/damage
   - ☐ other:
3. Date of event (mo/day/yr): 5/24/01
4. Date of this report (mo/day/yr): 5/30/01
5. Describe event or problem:

274.0, ♂ with longstanding history of pulmonary hypertension and chronic lung disease with worsening right heart failure. Placed on nitric oxide, Dobutamine + milrinone 5/21/01. Stabilized & transferred to ward 5/24/01. Acute Hct bleed with approx 400cc bloody brisk) a few hours after transfer. Transferred back to ICU, GI consult obtained – upper GI bleed thought to be secondary to NSAID + ASA vs stress ulcer. Had no further bleeding after starting ranitidine + sucralfate.

6. Relevant tests/laboratory data, including dates

5/20/01 Hct 39.3
5/24/01 Hct 42.4
5/25/01 Hct 42.2
5/26/01 Hct 42.2
5/28/01 Hct 43.0

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

Premature baby with severe bronchopulm. dysplasia; long standing pulmonary hypertension.

JUN – 7 2001

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
   #1 ASA 81mg p.o. qd
   #2 Vioxx 50mg p.o. qd
2. Dose, frequency & route
3. Therapy dates (if unknown, give duration) from/to (or best estimate)
4. Diagnosis for use (indication)
5. Event abated after use stopped or dose reduced: #1 ☐ yes ☐ no ☐ doesn't apply; #2 ☐ yes ☐ no ☐ doesn't apply
6. Lot # (if known)
7. Exp. date (if known)
8. Event reappeared after reintroduction: #1 ☐ yes ☐ no ☐ doesn't apply; #2 ☐ yes ☐ no ☐ doesn't apply
9. NDC # – for product problems only (if known)
10. Concomitant medical products and therapy dates (exclude treatment of event)

Nitric oxide 60ppm 12/breath of 100ppm oxygen @ 4L/min; Dobutamine 5mcg/kg/min, milrinone 0.5mcg/kg/min, Digoxin 0.125mg p.o. qd, Lasix 40mg IV bid, Lansoprazole 30mg p.o. qd, Sucralfate 1gm p.o. qid

D. Suspect medical device

1. Brand name
2. Type of device
3. Manufacturer name & address
4. Operator of device: ☐ health professional ☐ lay user/patient ☐ other:
5. Expiration date (mo/day/yr)
6. model # ____ catalog # ____ serial # ____ lot # ____ other #
7. If implanted, give date (mo/day/yr)
8. If explanted, give date (mo/day/yr)
9. Device available for evaluation? (Do not send to FDA) ☐ yes ☐ no ☐ returned to manufacturer on ____
10. Concomitant medical products and therapy dates (exclude treatment of event)

RECEIVED
JUN 0 8 2001
MEDWATCH CTU

E. Initial reporter

1. Name & address: [redacted] Phone # [redacted]
2. Health professional? ☑ yes ☐ no
3. Occupation: Clinical Practitioner
4. Initial reporter also sent report to FDA: ☐ yes ☐ no ☐ unk

JUN – 8 2001

FDA Form 3500A

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

CTU 145004

MEDWATCH

Individual Safety Report

3736053-3-00-01

for VOLUNTARY reporting of adverse events and product problems

Page ___ of ___

Form Approved: OMB No. 0910-0291 Expires:12/31/
See OMB statement on reverse

FDA Use Only

Triage unit sequence # 145032

A. Patient information

1. Patient identifier	2. Age at time of event: / or Date of birth:	3. Sex	4. Weight
2964 In confidence	76	☐ female ☒ male	___ lbs or ___ kgs

B. Adverse event or product problem

1. ☒ Adverse event and/or ☐ Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)
- ☐ death ___ (mo/day/yr)
- ☐ life-threatening
- ☒ hospitalization – initial or prolonged
- ☐ disability
- ☐ congenital anomaly
- ☐ required intervention to prevent permanent impairment/damage
- ☐ other: ___

3. Date of event (mo/day/yr)	4. Date of this report (mo/day/yr)
4-10-01	

5. Describe event or problem

MELANOTIC STOOLS
X 2 WEEKS

6. Relevant tests/laboratory data, including dates

INR = 3.5

DSS
JUN 11 2001

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

CTU 145032

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
- #1 WARFARIN
- #2 ASPIRIN / PIROXICAM

2. Dose, frequency & route used	3. Therapy dates (if unknown, give duration) from/to (or best estimate)
#1 5mg QD + 7.5mg MWF	#1 10-00 → /
#2 325mg QD / 20mg QD	#2 6-99 → / 2-01 →

4. Diagnosis for use (indication)	5. Event abated after use stopped or dose reduced
#1 A-F.D	#1 ☒ yes ☐ no ☐ doesn't apply
#2 PROPHYLAXIS / ARTHRITIS	#2 ☒ yes ☐ no ☐ doesn't apply

6. Lot # (if known)	7. Exp. date (if known)	8. Event reappeared after reintroduction
#1	#1	#1 ☐ yes ☐ no ☒ doesn't apply
#2	#2	#2 ☐ yes ☐ no ☒ doesn't apply

9. NDC # (for product problems only) - -

10. Concomitant medical products and therapy dates (exclude treatment of event)

ATENOLOL
NIFEDIPINE
TERAZOSIN

D. Suspect medical device

1. Brand name

2. Type of device

3. Manufacturer name & address

4. Operator of device
- ☐ health professional
- ☐ lay user/patient
- ☐ other: ___

5. Expiration date (mo/day/yr)

6.
- model # ___
- catalog # ___
- serial # ___
- lot # ___
- other # ___

RECEIVED
JUN 08 2001
MEDWATCH CTU

7. If implanted, give date (mo/day/yr)

8. If explanted, give date (mo/day/yr)

9. Device available for evaluation? (Do not send to FDA)
☐ yes ☐ no ☐ returned to manufacturer on ___ (mo/day/yr)

10. Concomitant medical products and therapy dates (exclude treatment of event)

E. Reporter (see confidentiality section on back)

1. Name, address & phone #

OVERTON BROOKS VA MEDICAL CENTER
510 EAST STONER AVENUE
SHREVEPORT, LOUISIANA 71101-4295
(318)-424-6001

2. Health professional?	3. Occupation	4. Also reported to
☒ yes ☐ no	RPh	☐ manufacturer ☐ user facility ☐ distributor

5. If you do NOT want your identity disclosed to the manufacturer, place an " X " in this box. ☒

FDA Mail to: MEDWATCH, 5600 Fishers Lane, Rockville, MD 20852-9787 or FAX to: 1-800-FDA-0178

FDA Form 3500 (6/93)

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

3740261-5-00-01

MEDWATCH
THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Aventis

Page 1 of 2

Form Approved by FDA: 05/22/95

Mfr report # US01-24477

UF/Dist report #

FDA Use Only

Patient information

1. Patient Identifier	2. Age at time	3. Sex	4. Weight
---	of event: or Date of Birth :	☐ female ☑ male	____ lbs or ____ kgs
In Confidence			

B. Adverse event or product problem

1. ☑ Adverse event and/or ☐ Product problem (e.g. defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

- ☐ death ____ (mo/day/yr)
- ☐ life-threatening
- ☑ hospitalization – initial or prolonged
- ☐ disability
- ☐ congenital anomaly
- ☐ required intervention to prevent permanent impairment/damage
- ☐ other: ____

3. Date of event (mo/day/yr)

4. Date of this report (mo/day/yr) AUG-8-2000

5. Describe event or problem

A PHARMACIST REPORTS THAT A MALE PATIENT EXPERIENCED PETECHIAE IN THE FACE, LEFT EYE SUBCONJUNCTIVAL HEMORRHAGE, AND A GASTROINTESTINAL (GI) BLEED. THE PATIENT RECEIVED ENOXAPARIN (1 MG/KG, Q 12H) FOR A TOTAL OF 10 DOSES. CONCOMITANT MEDICATIONS INCLUDED ASPIRIN AND PLAVIX, BOTH WERE CONSIDERED TO HAVE CONTRIBUTED TO THE BLEEDING EVENTS. ENOXAPARIN, ASPIRIN, AND PLAVIX WERE HELD. THE PATIENT HAD AN OPHTHALMOLOGY AND GI CONSULT. THE PATIENT RECOVERED AND ENOXAPARIN WAS NOT RECHALLENGED. HIS PAST MEDICAL HISTORY IS SIGNIFICANT FOR END-STAGE RENAL FAILURE, FOR WHICH HE IS RECEIVING DIALYSIS.

(THE MANUFACTURER OF PLAVIX WILL BE NOTIFIED OF THIS EVENT)

(SEE US01-24479 AND US01-24480, SAME REPORTER)

6. Relevant tests/laboratory data, including dates

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

END-STAGE RENAL FAILURE WITH DIALYSIS.

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
#1 LOVENOX 30 MG/0.3ML\30\AVENTIS PHARMA
#2 ASPIRIN

2. Dose, frequency & route used
#1 1 MG/KG\Q12H
#2

3. Therapy dates (if unknown, give duration) from/to (or best estimate)
#1
#2

4. Diagnosis for use (indication)
#1 NOT SPECIFIED
#2 UNKNOWN

5. Event abated after use stopped or dose reduced
#1 ☑ yes ☐ no ☐ doesn't apply
#2 ☐ yes ☐ no ☐ doesn't apply

6. Lot # (if known)
#1
#2

7. Exp. date (if known)
#1
#2

8. Event reappeared after reintroduction
#1 ☐ yes ☐ no ☑ doesn't apply
#2 ☐ yes ☐ no ☐ doesn't apply

9. NDC # – for product problems only (if known)

10. Concomitant medical products and therapy dates (exclude treatment of event)

G. All manufacturers

1. Contact office – name/address (& mfring site for devices)
AVENTIS PHARMACEUTICAL PRODUCTS Inc.
500 Arcola Road
P.O. Box 1200
Collegeville, PA 19426-0107

2. Phone number
(610) 454-8143

3. Report source (check all that apply)
☐ foreign
☐ study
☐ literature
☐ consumer
☑ health professional
☐ user facility
☐ company representative
☐ distributor
☐ other:

4. Date received by manufacturer (mo/day/yr)
APR-10-00

5. (A)NDA # 20-164
IND # ____
PLA # ____
pre-1938 ☐ yes
OTC product ☐ yes

6. If IND, protocol #

7. Type of report (check all that apply)
☐ 5-day ☐ 15-day
☐ 10-day ☑ periodic
☑ Initial ☐ follow-up # ____

8. Adverse event term(s)
PETECHIAE, FACE
LEFT EYE SUBCONJUCTIVAL HEMORRHAGE
GASTROINTESTINAL BLEED

9. Mfr. report number
US01-24477

E. Initial reporter

1. Name, address & phone #
[redacted]
HOSPITAL
STREET
UNITED STATES

JUN 1 2 2001

2. Health professional?
☑ yes ☐ no

3. Occupation
PHARMACIST

4. Initial reporter also sent report to FDA
☐ yes ☐ no ☑ unk

FDA Facsimile Form 3500A

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

Manufacturer report number: US01-24477

Manufacturer name:

AVENTIS PHARMACEUTICAL PRODUCTS Inc.
500 Arcola Road
P.O. Box 1200
Collegeville, PA 19426–0107

3740261-5-00-02

Suspect medication(s)

1. **Name** (give labeled strength & mfr/labeler, if known)
#3 PLAVIX
#4

2. **Dose, frequency & route used**
#3
#4

3. **Therapy dates** (if unknown, give duration) from/to (or best estimate)
#3
#4

4. **Diagnosis for use** (indication)
#3 UNKNOWN
#4

5. **Event abated after use stopped or dose reduced**
#3 ☐ yes ☐ no ☐ doesn't apply
#4 ☐ yes ☐ no ☐ doesn't apply

6. **Lot #** (if known)
#3
#4

7. **Exp. date** (if known)
#3
#4

8. **Event reappeared after reinfroduction**
#3 ☐ yes ☐ no ☐ doesn't apply
#4 ☐ yes ☐ no ☐ doesn't apply

9. **NDC #** – for product problems only (if known)

10. **Concomitant medical products and therapy dates** (exclude treatment of event)

JUN 14 2001

Individual Safety Report

3742129-7-00-01

WATCH FORM ■ UPDATES

MEDWATCH

THE FDA MEDICAL PRODUCT REPORTING PROGRAM

For VOLUNTARY reporting by health professionals of adverse events and product problems

Page ___ of ___

Form Approved: OMB No. 0910-0291 Expires: 12/31/94
See OMB statement on reverse

FDA Use Only (AHFS)

Triage unit sequence #: 145693

A. Patient information

1 Patient identifier	2 Age at time of event:	3. Sex	4 Weight
831731 In confidence	or Date of birth: [redacted]	☐ female ☒ male	___ lbs or ___ kgs

B. Adverse event or product problem

1 ☒ Adverse event and/or ☐ Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

- ☐ death
- ☐ life-threatening
- ☒ hospitalization – initial or prolonged
- ☐ disability
- ☐ congenital anomaly
- ☐ required intervention to prevent permanent impairment/damage
- ☐ other

3 Date of event	4. Date of this report
10/5/00	3/20/01

5. Describe event or problem

Admitted from ER c acute onset of coffee-ground emesis c transient hypotension. Hx of melena or diaphoresis. The patient was on ASA. Hx of gastritis but no PUD. Hemoccult (+). GI consult notes and ulcer causing bleed. Suspect Mallory-Weiss tear from vomiting. Upper endoscopy ruled out Mallory-Weiss tear but evidence of hemorrhaging. Emesis while in hospital & no evidence of bleeding in NG tubing or fluid drawn from tube. Pt remained hemodynamically stable while in hospital.

6. Relevant tests/laboratory data, including dates

	HCT	HgB	
			INR 10/5 1.14
10/5	11.1	34.5	Albumin 10/5 2.9
10/6	10.5	33.4	
10/7	11.1	34.4	
10/9	12.4	38.6	

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

HTN
CAD
dementia due to ETOH
Alzeihmer's
arthritis
multiple CVA's
BPH c urinary retention
PVD
diverticulosis
UTI's
anemia

C. Suspect medication(s)

1. Name (give labeled strength & manufacturer, if known)

#1 ASA po (don't know strength)
#2 Fosamax 35mg po qwk

2. Dose, frequency & route used

#1 Unknown
#2 35mg po qwk

3. Therapy dates (if unknown, give duration)

#1 all 3 this prior to admission
#2

4. Diagnosis for use (indication)

#1 Prophylaxis
#2 anemia

5. Event abated after use stopped or dose reduced

#1 ☒ yes ☐ no ☐ doesn't apply
#2 ☒ yes ☐ no ☐ doesn't apply

6. Lot # (if known)

#1
#2

7. Exp. date (if known)

#1
#2

8. Event reappeared after reintroduction

#1 ☐ yes ☐ no ☒ doesn't apply
#2 ☐ yes ☐ no ☒ doesn't apply

9. NDC # (for product problems only)

- -

10. Concomitant medical products and therapy dates (exclude treatment of event)

Levaquin 500mg po q 48h
Fosamax 35mg po qwk
Prevacid 30mg bid
Nexium 5mg po qd
MVI
Depakote 250mg po bid
Risperdal 1mg po bid
Ferrous Sulfate 325mg po tid
KCl 10 meq po tid

D. Suspect medical device

1. Brand name

2. Type of device

3. Manufacturer name & address

4. Operator of device
- ☐ health professional
- ☐ lay user/patient
- ☐ other

5. Expiration date

6.
model # RECEIVED
catalog #
serial # JUN 20 2001
lot #
other # MEDWATCH CTU

7. If implanted, give date

8. If explanted, give date

9. Device available for evaluation? (Do not send to FDA)
☐ yes ☐ no ☐ returned to manufacturer on ___

10. Concomitant medical products and therapy dates (exclude treatment of event)

E. Reporter (see confidentiality section on back)

1. Name, address & phone #

[redacted]

2. Health professional? ☒ yes ☐ no

3. Occupation: Pharmacy Intern

4. Also reported to
- ☐ manufacturer
- ☐ user facility
- ☐ distributor

5. If you do NOT want your identity disclosed to the manufacturer, place an " X " in this box. ☐

Mail to: MEDWATCH, 5600 Fishers Lane, Rockville, MD 20852-9787
or FAX to: 1-800-FDA-0178

FDA Form 3500 (6/93)

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

CTW145693

JUN 20 2001

Individual Safety Report

3742362-4-00-01

MEDWatch

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

CDER

Approved by FDA on 10/20/93

Triage unit sequence # 145593

A. Patient Information

1. Patient Indentifier: [redacted] | 2. DOB: [redacted] AGE: 78 yrs | 3. Sex: MALE | 4. Weight: 0.0

B. Adverse Event or Product Problem

1. [X] Adverse Event [ ] Product problem

2. Outcomes attributed to adverse event
- [ ] death:
- [ ] life-threatening
- [X] Hospitalization initial or prolonged -------
- [ ] disability
- [ ] congenital anomaly
- [X] required intervention to prevent impairment/damage
- [ ] other

3. Date of event: 08/11/00

4. Date of this report: 05/02/01

5. Describe event or problem
GI bleed

6. Relevant test/laboratory data, including dates

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MEDWATCH CTU

7. Other relevant History, including preexisting medical conditions

C. Suspect Medication(s)

1. Name	2. Dose, frequency & route used	3. Therapy dates	4. Diagnosis for use (indication)	5. Event abated after use stopped or dose reduced?	6. Lot # (if known)	7. Exp. date	8. Event reappeared after reintroduction
#1 : ASPIRIN	#1:	#1 :	#1:	#1: [N/A]	#1:	#1:	#1: [ ]

9. (Not applicable to adverse drug event reports)

10. Concomitant medical products/therapy dates (exclude treatment)

D. Suspect Medical Devices

Note: Please use the actual MedWatch form if the event involves a suspected device as well as a suspect drug

E. Reporter

1. Name, address & phone #: [redacted]
DEPT OF VA MEDICAL CENTER
3200 VINE ST
CINCINNATI, OH 45220
[redacted]

2. Health professional? [YES]

3. Occupation: PHARMACY RESID

4. Reported to Mfr. [NO]

5. If you don't want your identity disclosed to the Manufacturer, place an "X" in the box. [X]

Mail to: MedWatch
5600 Fishers Lane
Rockville, MD 20852-9787

or FAX to:
1-800-FDA-0178

FDA Form 3500

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

CTV145593

Individual Safety Report

3742368-5-00-01

MEDWATCH

FOR VOLUNTARY reporting by health professionals of adverse events and product problems

Page of

444

1455 70

A. Patient information

1. Patient identifier: [redacted]1188 — In confidence
2. Age at time of event: 57 or Date of birth: [redacted]
3. Sex: ☐ female ☒ male
4. Weight: 177 lbs or ___ kgs

B. Adverse event or product problem

1. ☒ Adverse event and/or ☐ Product problem (e.g., defects/malfunctions)
2. Outcomes attributed to adverse event (check all that apply)
   - ☐ death
   - ☐ life-threatening
   - ☒ hospitalization – initial or prolonged
   - ☐ disability
   - ☐ congenital anomaly
   - ☐ required intervention to prevent permanent impairment/damage
   - ☐ other:
3. Date of event: 12/19/00
4. Date of this report: 01/30/01
5. Describe event or problem

VA

Nursing home pt presented w/ blackstools and coffee ground blood on 12/19 - coumadin & ASA stopped. INR 6.87 and Hg 5.5 at that time. Pt then proceeded to have large emesis w/ large and small clots and passed blood per rectum. He was transferred to AEU and there while trying to insert NGT pt vomitted large amt of dark blood IVF NS, 2U FFP, 2U PRBC + SQ VIT K was given. Was transferred to ICU and 2 more units of FFP/PRBC given and placed on IV H_2 blockers On 12/20 EGD revealed linear esophageal ulceration and evidence of recent bleed. Lansoprazole 60mg po bid was started and anticoags held. Pt had previous EGD that revealed PUD on 12/9. 2U PRBC given: INR ↓ 1.10 (12/20) On 12/26 pt transferred back to nursing home w/ Hg 9.1 & bk he was progressively improving. Warfarin was not resumed and pt switched to Heparin 5000U SC BID.

6. Relevant tests/laboratory data, including dates

Date	Hg	Hct	INR	
12/19	5.5	16.1	6.87	
12/19			9.44	
12/20	8.4	23.7	1.10	
12/21	9.3	27	0.88	
12/[illegible]	10.9	[illegible]	2.36	

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

- HTN
- Depression
- DM
- Seizure d/o
- CAD
- DVT (4 years)

h/o PUD

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
   - #1 Warfarin ~~2.5mg po qd~~
   - #2 Heparin
2. Dose, frequency & route used
   - #1 2.5mg PO QD
   - #2
3. Therapy dates (if unknown, give duration)
   - #1 ~ 4 years
   - #2
4. Diagnosis for use (indication)
   - #1
   - #2
5. Event abated after use stopped or dose reduced
   - #1 ☐ yes ☐ no ☐ doesn't apply
   - #2 ☐ yes ☐ no ☐ doesn't apply
6. Lot # (if known)
   - #1
   - #2
7. Exp. date (if known)
   - #1
   - #2
8. Event reappeared after reintroduction
   - #1 ☐ yes ☐ no ☐ doesn't apply
   - #2 ☐ yes ☐ no ☐ doesn't apply
9. NDC # (for product problems only)
10. Concomitant medical products and therapy dates (exclude treatment of event)

D. Suspect medical device

1. Brand name
2. Type of device
3. Manufacturer name & address

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MEDWATCH CTU

4. Operator of device
   - ☐ health professional
   - ☐ lay user/patient
   - ☐ other:
5. Expiration date
6. model # / catalog # / serial # / lot # / other #
7. If implanted, give date
8. If explanted, give date
9. Device available for evaluation? ☐ yes ☐ no ☐ returned to manufacturer on ___ (Do not send to FDA)
10. Concomitant medical products and therapy dates (exclude treatment of event)

E. Reporter (see confidentiality section on back)

1. Name
   [redacted]
   North Chicago VA Medical Center
   3001 Green Bay Road
   [redacted] North Chicago, Illinois 60064
2. Health professional? ☒ yes ☐ no
3. Occupation: Pharmacist
4. Also reported to
   - ☐ manufacturer
   - ☐ user facility
   - ☐ distributor
5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box. ☐

JUN 2 8 2001

FDA

Mail to: MEDWATCH, 5600 Fishers Lane, Rockville, MD 20852-9787 or FAX to: 1-800-FDA-0178

FDA Form 3500 (6/93)

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

CTV145 570

#1 probable ADR

Individual Safety Report

3742368-5-00-02

145570

ADR CONTINUATION REPORTING SHEET

PATIENT: ● 1188

PAST MEDICAL HISTORY	DM HTN CAD DVT Depression seizure d/o.

MEDICATIONS UPON ADMISSION			

PHYSICAL EXAM	BP TEMP	OTHER PT. INFO	
	PULSE RESP		

EKG

LABS						
12/15 INR 2.3	12/19 (1:46)		12/19 H 9 5.5			
PTT 34.2	INR 6.87		Hct			
PT 27.5.	PTT 47.2					
12/19 INR 9.4	PT 73.9		Hct			
(19:16) PTT 47.2	INR ↑ 1.6.					
PT 99						

nursing home

SEQUENCE OF EVENTS	12/19/ 4:43A - black stool occult blood 11:43 lab done - critical lab report hold warfarin 18:06 large emesis of lg/sm clots + pooling blood 05:30 per rectum. transferred to AEU.

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145570

Individual Safety Report

3742368-5-00-03

145570

PAGE 2 OF ADR CONTINUATION REPORTING SHEET

PATIENT: _____

SEQUENCE OF EVENTS

(12/19) 17:45 vomit leg amt dk blood when in NG tube.
IVF NS 2U FFP ; PRBC SC Vit K
EGD candidal esophagitis and DU.
19:41 4U FFP 4U PRBC total.
placed on H2 blockers.
23:51 one more hematemesis ; one melena.
(3rd. FFP/PRBC.)
(2/20) Endoscopy. mid esoph linear ulceration ; exudation w/ evedence
12hr of recent bleed. no active bleeding AT present time
coffee grounds in stomach. 7AM 1 more hematemesis
↑ Lansoprazole to 60mg po bid. no NSAID. no anticoagc.
14:24 pink tinge urine IVF → D5 1/2NS Vit K SQ.
2U ~~FFP~~ PRBC. large amt blackish stool

(12/21) – 14:42 1 tarry mod loose stool. IVF → D5 W D/C.
18:54 no want po liquids. tiny clots in urine L hemipa
20:20. pink urine
(12/22) – 6:49 amber colored urine
11:16. cont Lansop 60mg BID for 8 wks then ↓ dose to 30mg BID.
12:42 no active bleeding.
started on Lansop 30 mg bid on 12/9/00

(12/23) 1:30 amber urine
9:18 " "
21:20 cloudy yellow.
(12/24) 9:49. will transfer on 12/26.
10:11 dk urine
(12/26) transferred to NH.
stable
12/27 stable
12/29 no c/o N/V NO GI bleed noted.

145570

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Individual Safety Report

3742433-2-00-01

The FDA Medical Products Reporting Program

For VOLUNTARY reporting by health professionals of adverse events and product problems

Triage Unit Sequence # 145716

Page 1 of 1

[redacted] ELECTRONIC 3500 FORM ADAPTATION, Version 1.01, September 1997

A. Patient Information

1. Patient Identifer	2. Age at time of event:	3. Sex	4. Weight
[redacted] 3309 (In confidence)	or Date of birth: [redacted]	M	lbs 0 kgs

B. Adverse Event or Product Problem

1. ☑ Adverse Event and/or ☐ Product Problem

2. Outcomes attributed to adverse event

- ☐ Death
- ☑ Life-threatening
- ■ Hospitalization - initial
- ☐ Hospitalization - prolonged
- ☐ Disability
- ☐ Congenital anomaly
- ☑ Required intervention to prevent permanent impairment/damage

3. Date of event (mo/day/yr): 5/3/01

4. Date of this report (mo/day/yr): 5/1/01

5. Describe event or problem

A pharmacist reported that a patient began taking Goody's Powders (aspirin) on an unspecified date for an unspecified indication. On 3-May-01 the patient experienced GASTROINTESTINAL BLEEDING. The reaction was treated by discontinuation of the medication, administration of blood products and ADMISSION TO THE HOSPITAL. The reaction was reported to have resolved.

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6. Relevant tests/laboratory data, including dates

Serum Creatinine:

hematocrit 19 %

7. Other relevant history, including preexisting medical conditions

Allergies: NKA

JUN 19 2001

CTV145716

C. Suspect Medication(s)

1. Name (give labeled strength, mfr/labeler, if known)

#1 goody's powder
#2

2. Dose, frequency, route used			3. Therapy Dates (from/to)	
#1	5 x a day	PO	#1	/ 05/03/01
#2			#2	/

4. Diagnosis for use (indication)	5. Event abated after use stopped or dose reduced
#1	#1 Yes
#2	#2

6. Lot # (if known)	7. Exp. date	8. Event reappeared after reintroduction
#1	#1	#1 Unknown
#2	#2	#2

9. NDC # (for product problems only)

10. Concomitant medical products

DSS
JUN 20 2001

D. Suspect Medical Device

These fields not used for electronic 3500 reporting at [redacted]

Internal ADR Event Coding

Reaction 1: bleeding
Reaction 2: hemeternsis, melena
Reaction 3:
Reaction 4:
Reaction 5:

E. Reporter (see confidentiality section on back

1. Name, address and phone #

ADR Program Coordinator / Drug Information Service
Department of Pharmacy and Drug Information
[redacted] Box [redacted]
[redacted]
[redacted]

2. Health Professional	3. Occupation	4. Also reported to
☑ Yes ☐ No	Pharmacist	☐ manufacturer ☑ user facility ☐ distributor

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box. ☐

FDA Mail to: MEDWATCH, 5600 Fishers Lane, Rockville MD 20852 or FAX to: 1-800-FDA-0178

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event

3742525-8-00-01

MedWatch

The FDA Medical Products Reporting Program

Health Division

For use by user-facilities, distributors and manufacturers for MANDATORY reporting

Page 1

Merck Facsimile of FDA Form 3500A
Approved by FDA (10/21/93)

Mfr report #	WAES 01021272
UF/Dist report #	
	FDA Use Only

A. Patient information

1. Patient identifier	2. Age at time of event:	3. Sex	4. Weight
[redacted] in confidence	or 80 years Date of Birth: [redacted]	[ ] Female [X] Male	154 lbs

B. Adverse event or product problem

1. [X] Adverse event and / or [ ] Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

- [ ] death ____ (mo/day/yr)
- [X] life-threatening
- [X] hospitalization-initial or prolonged
- [ ] disability
- [ ] congenital anomaly
- [ ] required intervention to prevent permanent impairment/damage
- [X] other: important medical

3. Date of event (mo/day/yr): 02/??/01

4. Date of this report (mo/day/yr): 06/13/01

5. Describe event or problem

Information has been received from a physician concerning an 80 year old hospitalized retired white male with hypertension, benign prostatic hyperplasia, diet controlled diabetes, chronic renal insufficiency, coronary artery disease, and a penicillin allergy, and a history of lipoma removal, transurethral resection of the prostate, and smoking (quit 20 years ago) who was placed on therapy with tirofiban HCl (dose not reported) for the treatment of non-Q-wave myocardial infarction. Concomitant suspect therapy included heparin (dose, duration, and indication not reported) and aspirin (total daily dose, duration, and indication not reported). Concomitant therapy included isosorbide dinitrate (Isordil), metoprolol tartrate (Lopressor), methyldopa (MSD), desipramine, fosinopril, nifedipine, clonidine, and docusate sodium (Colace). The physician reported that in February 2001 (exact date unknown), the patient presented at the hospital with a non-Q-wave myocardial infarction. Laboratory findings revealed that the patient's troponin peaked at 11 and serum creatinine was 2.1. At approximately 1500, the patient was started

(Continued on Additional Page)

6. Relevant tests/laboratory data, including dates

Refer to Additional Page

7. Other relevant history, including preexisting medical conditions (e.g., allergies,race,pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

MEDICAL HISTORY: lipoma surgery; smoking; transurethral prostatectomy
CONCURRENT CONDITIONS: arm pain; benign prostatic hyperplasia; chronic renal insufficiency; coronary artery disease; loose stool; penicillin allergy; diabetes mellitus; epigastric pain; hospitalization; hypertension

FDA Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)

#1 INJ AGGRASTAT 0.4 microgm/kg/min

#2 heparin Unk

(Continued on Additional Page)

2. Dose, frequency & route used	3. Therapy dates (from/to) (if unknown, give duration)
#1 Unk/Unk/IV	#1 02/??/01 - 02/??/01
#2 Unk/Unk/IV	#2 02/??/01 - 02/??/01

4. Diagnosis for use (indication)

#1 non-Q-wave myocardial infarction

#2 Unknown

5. Event abated after use stopped or dose reduced.

	yes	no	N/A	unk
#1	X			
#2				X

6. Lot # (if known)

#1

#2

7. Exp date (if known)

#1

#2

8. Event reappeared after reintroduction

	yes	no	N/A	unk
#1			X	
#2				X

9. NDC # - for product problems only (if known)

Unknown

10. Concomitant medical products and therapy dates (exclude treatment of event)

ALDOMET (METHYLDOPA)	Unk -Unk
COLACE	Unk -Unk

(Continued on Additional Page)

G. All manufacturers

1. Contact office - name/address

Merck Human Health Division
Merck & Co., Inc.
P.O. Box 4
West Point, PA 19486-0004

ATTN: Worldwide Product Safety

2. Phone Number: (610)397-2416

3. Report source (check all that apply)

- [ ] foreign
- [ ] study
- [ ] literature
- [ ] consumer
- [X] health professional
- [ ] user facility
- [X] company representative
- [ ] distributor
- [ ] other

4. Date received by manufacturer (mo/day/yr): 02/15/01

5. (A)NDA # 20912
IND #
PLA #
pre-1938 [ ] yes
OTC product [ ] yes

6. If IND, protocol #

7. Type of report
- [ ] 5-day
- [ ] 15-day
- [ ] 10-day
- [X] periodic
- [X] initial
- [ ] Follow-up# ____

9. Mfr. report number: WAES 01021272

8. Adverse event term(s)

GASTROINTESTINAL BLEEDING; EPISTAXIS; GINGIVAL HEMORRHAGE; HEMATOMA

E. Initial reporter

1. Name, address & phone # [redacted]

233 EAST HURON
LAKESIDE VETERAN'S HOSPITAL
CHICAGO, IL 60611

2. Health professional?
[X] YES [ ] NO

3. Occupation: M.D.

4. Initial reporter also sent report to FDA
[ ] yes [ ] no [X] unk

JUN 15 2001

B. Adverse event or product problem

5. Describe event or problem

on therapy with IV heparin and tirofiban HCl, injection (form), 0.4 microgm/kg/min (total daily dose and duration not reported). Eight hours after starting therapy with tirofiban HCl (at 2000-2100 hrs), the patient had bleeding of the gums and a small lateral tongue hematoma. The patient also had black tarry stools and bright red blood per rectum. Laboratory findings revealed that the patient's hemoglobin had decreased from 13 to 12 to 9. The patient's initial platelet count was approximately 190,000, and a subsequent platelet count was 160,000-170,000. The patient's activated partial thromboplastin time (PTT) was initially 75-77, and a subsequent PTT was 80. Therapy with tirofiban HCl was discontinued. Subsequently the patient recovered in 12 hours. The physician reported that the patient underwent successful cardiac catheterization on 14-FEB-2001 and did not have any problems post-procedure.

Additional information has been received from the physician via medical records. It was reported that the patient's date of birth was 11-FEB-1920 (conflicting from previously reported information). Two days prior to admission, the patient began to develop epigastric pain, 5/10, without radiation. The patient had no shortness of breath or diaphoresis. The pain has remained constant until the day of admission. He stated that he felt like he had a flu. In the past three to six months, he had noted sharp shooting pain down the left arm whenever he exerted himself, and these pains disappeared once he rested. He did have a loose, nonbloody bowel movement on the day of admission (13-FEB-2001). Laboratory findings on admission were hemoglobin 13.5, platelets 164, potassium 5.9, creatinine 2.0, creatinine phosphokinase (CPK) 324, CPK-MB 6.8, index 2.1, and a troponin of 19. An electrocardiogram showed sinus bradycardia with a heart rate of 55, left axis deviation, LVH with repolarization abnormalities, peak T waves in v2 and v3, ST depression in v5 and v6, unchanged from old EKG. The patient was started on intravenous heparin as well as tirofiban HCl 0.4 mcg per minute per kilogram with holding of metoprolol tartrate (Lopressor) for his bradycardia, and the patient was admitted to the coronary care unit. The patient during the course of his hospitalization had no further episodes of chest or epigastric discomfort. The patient's initial cardiac enzymes were his peak enzymes. The patient's heparin drip was discontinued because of melanic stool with a drop in hemoglobin at 9.2. It was reported that therapy with aspirin was discontinued due to a gastrointestinal bleed during the course of his hospitalization. The patient was evaluated by Gastroenterology during the course of his hospitalization, who felt that the patient likely had an upper GI source for his associated bleed. It was reported that the patient did have one bout of epistaxis. The patient underwent a cardiac catheterization on 15-FEB-2001, that showed a ejection fraction of 45% and three-vessel disease. The patient subsequently had a questionable hematoma and an ultrasound of his groin that showed no pseudoaneurysm, no fistula, and no hematoma. The patient was evaluated by Cardiology, and it was recommended that the patient was not a surgical candidate for a coronary artery bypass graft. The patient had a relatively uncomplicated hospital course. He was discharged to home on 24-FEB-2001.

The physician felt that the patient's gastrointestinal hemorrhage, gingival hemorrhage, and hematoma prolonged hospitalization, were immediately life-threatening and were other medical events.

No additional information is expected.

6. Relevant tests/laboratory data, including dates

DIAGNOSTIC TEST

Tests	Date	Value	Unit	Normal Range
electrocardiogram	02/13/01			
Comment: sinus bradycardia with heart rate of 55, left axis deviation, LVH with repolarization abnor, peak T				
cardiac catheterization	02/15/01			
Comment: 3 vessel disease				
ultrasound	02/15/01			
Comment: showed no pseudoaneurysm, fistula, or hematoma				

LABORATORY RESULTS

Tests	Date	Value	Unit	Normal Range
APTT	02/??/01	75-77		
APTT	02/??/01	80		
hemoglobin	02/??/01	13		
hemoglobin	02/??/01	12		
hemoglobin	02/??/01	9		
platelet count	02/??/01	190,000		
Comment: approximately				
platelet count	02/??/01	160,000-170,000		
serum TnI	02/??/01	[illegible]		
serum creatinine	02/??/01	[illegible]		
hemoglobin	02/13/01	13.5		
hemoglobin	02/??/01	9.2		

platelet count	02/13/01	164
serum TnI	02/13/01	19
serum creatine kinase	02/13/01	324
serum creatine kinase isoenzyme MB	02/13/01	6.8
serum creatinine	02/13/01	2.0
serum potassium	02/13/01	5.9
left ventricular ejection fraction	02/15/01	45 %

C. Suspect medication(s)

1. Name (Given labeled strength & mfr/labeler, if known)
   #3 aspirin Unk

2. Dose, frequency & route used
   #3 Unk/Unk/Unk

3. Therapy dates (from/to) (if unknown, give duration)
   #3 Unk - 02/??/01

4. Diagnosis for use (indication)
   #3 Unknown

5. Event abated after use stopped or dose reduced

	YES	NO	N/A	UNK
#3				X

6. Lot # (if known)
   #3

7. Exp date (if known)
   #3

8. Event reappeared after reintroduction

	YES	NO	N/A	UNK
#3				X

C. Suspect medication(s)

10. Concomitant medical products and therapy dates (exclude treatment of event)

ISORDIL	Unk - Unk
LOPRESSOR	Unk - 02/??/01
clonidine	Unk - Unk
desipramine	Unk - Unk
fosinopril	Unk - Unk
nifedipine	Unk - Unk

Individual Safety Report

3748711-5-00-01

MEDWATCH

For VOLUNTARY reporting by health professionals of adverse events and product problems

Page 1 of 1 C

Form Approved: OMB No. 0910-0291 Expires: 4/30/03
See OMB statement on reverse

FDA Use Only

Triage unit sequence # 146254

A. Patient information

1. Patient identifier	2. Age at time of event: / or Date of birth:	3. Sex	4. Weight
[redacted] In confidence	unknown / unknown	☐ female ☐ male	____ lbs or ____ kgs

B. Adverse event or product problem

1. ☐ Adverse event and/or ☐ Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)
- ☐ death ____ (mo/day/yr)
- ☐ life-threatening
- ☐ hospitalization – initial or prolonged
- ☐ disability
- ☐ congenital anomaly
- ☐ required intervention to prevent permanent impairment/damage
- ☐ other: ____

3. Date of event (mo/day/yr): Apr-02-01

4. Date of this report (mo/day/yr): Apr-29-01

5. Describe event or problem

A female patient with a history of gastritis and peptic ulcer disease from aspirin 4 years ago, restarted aspirin 325mg daily 3 to 4 days ago. She was admitted into the hospital on Apr-02-01 for hematemesis. The night she was admitted she had 2 episodes of "coffee-ground' emesis. Prior to hospitalization the patient had no alcohol or non-steroidal anti-inflammatory drug use. In the emergency department she had a nasogastric tube placed for lavage. Aspirin therapy was discontinued. She was treated with Zantac 50 mg intravenous every 8 hours, was transfused with 2 units of packed red blood cells and was given intravenous fluids.

6. Relevant tests/laboratory data, including dates

unknown

RECEIVED
JUN 2 8 2001
MEDWATCH CTU

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

peptic ulcer disease and gastritis from aspirin about 4 years ago.

JUN 2 8 2001

C. Suspect medication(s)

1. Name (give labeled strength & manufacturer, if known)
- #1 aspirin
- #2

2. Dose, frequency & route used
- #1 325 mg po qd
- #2

3. Therapy dates (if unknown, give duration) from/to (or best estimate)
- #1
- #2

4. Diagnosis for use (indication)
- #1 unknown
- #2

5. Event abated after use stopped or dose reduced
- #1 ☐ yes ☐ no ☐ doesn't apply
- #2 ☐ yes ☐ no ☐ doesn't apply

6. Lot # (if known)
- #1
- #2

7. Exp. date (if known)
- #1
- #2

8. Event reappeared after reintroduction
- #1 ☐ yes ☐ no ☐ doesn't apply
- #2 ☐ yes ☐ no ☐ doesn't apply

9. NDC # (for product problems only)
- – –

10. Concomitant medical products and therapy dates (exclude treatment of event)

unknown

D. Suspect medical device

1. Brand name

2. Type of device

3. Manufacturer name & address

4. Operator of device
- ☐ health professional
- ☐ lay user/patient
- ☐ other: ____

5. Expiration date (mo/day/yr)

6.
- model # ____
- catalog # ____
- serial # ____
- lot # ____
- other # ____

7. If implanted, give date (mo/day/yr)

8. If explanted, give date (mo/day/yr)

9. Device available for evaluation? (Do not send to FDA)
- ☐ yes ☐ no ☐ returned to manufacturer on ____ (mo/day/yr)

DSS

10. Concomitant medical products and therapy dates (exclude treatment of event)

JUN 2 8 2001

E. Reporter (see confidentiality section on back)

1. Name & address

phone # [redacted]

[redacted] Drug Center [redacted] STE [redacted]

2. Health professional? ☐ yes ☐ no

3. Occupation: pharmacist

4. Also reported to
- ☐ manufacturer
- ☐ user facility
- ☐ distributor

5. If you do NOT want your identity disclosed to the manufacturer, place an " X " in this box. ☐

Mail to: MEDWATCH, 5600 Fishers Lane, Rockville, MD 20852-9787 or FAX to: 1-800-FDA-0178

FDA

CTU 146254

FDA Form 3500 (1/98) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event

PLEASE TYPE OR USE BLACK INK

T-067 P.005/005 F-124 FROM-

JUN-27-2001 15:48

Jul-03-01 07:45am From-BT PHARMACY OFFICE T-131 P.004/020 F-380

Individual Safety Report

3751168-1-00-01

[redacted] vents and product problems

Page ___ of ___

114489

A. Patient information

1. Patient identifier	2. Age at time of event: or Date of birth:	3. Sex	4. Weight
[redacted]6738 in confidence	53	☐ female ☒ male	___ lbs or ___ kgs

B. Adverse event or product problem

1. ☒ Adverse event and/or ☐ Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)
- ☐ death ___ (mo/day/yr)
- ☐ life-threatening
- ☐ hospitalization – initial or prolonged
- ☐ disability
- ☐ congenital anomaly
- ☐ required intervention to prevent permanent impairment/damage
- ☐ other: ___

3. Date of event (mo/day/yr): 5/11/01

4. Date of this report (mo/day/yr): 5/11/01

5. Describe event or problem

Pt taking daily aspirin plus alka seltzer for 1-2 weeks prior to admission for abdominal pain. Presents to ECS with c/o dizziness, hematemesis and melena x 3 days. NGL ⊖. Pt admitted ICU. EGD: large ulcer, given 2 units PRBCs, lansoprazole and aspirin changed to clopidogrel.

6. Relevant tests/laboratory data, including dates

Hct 37 → 27

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

HTN, CVA

MEDWATCH CTU

JUL 03 2001

Severe Probable

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
- #1 aspirin
- #2 alka-seltzer

2. Dose, frequency & route used
- #1 325mg po QD
- #2 prn stomach pain

3. Therapy dates (if unknown, give duration) from/to (or best estimate)
- #1
- #2

4. Diagnosis for use (indication)
- #1 CVA
- #2

5. Event abated after use stopped or dose reduced
- #1 ☐ yes ☐ no ☐ doesn't apply
- #2 ☐ yes ☐ no ☐ doesn't apply

6. Lot # (if known)
- #1
- #2

7. Exp. date (if known)
- #1
- #2

8. Event reappeared after reintroduction
- #1 ☐ yes ☐ no ☐ doesn't apply
- #2 ☐ yes ☐ no ☐ doesn't apply

9. NDC # (for product problems only)
- – –

10. Concomitant medical products and therapy dates (exclude treatment of event)

D. Suspect medical device

1. Brand name

2. Type of device

3. Manufacturer name & address

4. Operator of device
- ☐ health professional
- ☐ lay user/patient
- ☐ other: ___

5. Expiration date (mo/day/yr)

6.
- medcl # RECEIVED
- catalog # JUL 03 2001
- serial #
- lot #
- other #

7. If implanted, give date (mo/day/yr) DSS

8. If explanted, give date (mo/day/yr) 07 03 2001

9. Device available for evaluation? (Do not send to FDA)
- ☐ yes ☐ no ☐ returned to manufacturer on ___ (mo/day/yr)

10. Concomitant medical products and therapy dates (exclude treatment of event)

[redacted]

E. Reporter (see confidentiality section on back)

1. Name, address & phone #

[redacted] Pharmd, Pharmacy (119)
Maryland VA Health Care System
10 N. Greene St, Balt MD 21201

2. Health professional? ☒ yes ☐ no

3. Occupation: Clinical Pharmacist

4. Also reported to
- ☐ manufacturer
- ☐ user facility
- ☐ distributor

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box. ☐

FDA

Mail to: MEDWATCH, 5600 Fishers Lane, Rockville, MD 20852-9787 or FAX to: 1-800-FDA-0178

FDA Form 3500 (6/93) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

CTU 114489

Individual Safety Report

3751170-X-00-01

...ents and product problems

Page ___ of ___

Mfgr. Rpt. sequence # 146490

Patient identifier	2. Age at time of event: or Date of birth:	3. Sex	4. Weight
3617 In [redacted]	79	☐ female ☒ male	___ lbs or ___ kgs

B. Adverse event or product problem

1. ☒ Adverse event and/or ☐ Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)
- ☐ death ___ (mo/day/yr)
- ☐ life-threatening
- ☐ hospitalization – initial or prolonged
- ☐ disability
- ☐ congenital anomaly
- ☐ required intervention to prevent permanent impairment/damage
- ☐ other: ___

3. Date of event (mo/day/yr): 5/14/01

4. Date of this report (mo/day/yr): 5/18/01

5. Describe event or problem

Pt presented to ECS with one month c/o dizziness, dark stools and coffee ground emesis. NG lavage ⊕. Pt admitted to ICU, called in for MI. EGD: large duodenal ulcer/tumor, H. Pylori ⊕. Pt received 7 units PRBCs. ? (lansoprazole, oxacillin, clarithromycin)

6. Relevant tests/laboratory data, including dates

Hct 32 → 14.9

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

MI, AFib, HTN, DM, prostate CA, remote PUD

Severe probable

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
- #1 aspirin
- #2 ibuprofen

2. Dose, frequency & route used
- #1 325mg QD
- #2 prn 600mg

3. Therapy dates (if unknown, give duration) (from/to (or best estimate))
- #1 ___
- #2 ___

4. Diagnosis for use (indication)
- #1 CAD
- #2 bone pain

5. Event abated after use stopped or dose reduced
- #1 ☐ yes ☐ no ☐ doesn't apply
- #2 ☐ yes ☐ no ☐ doesn't apply

6. Lot # (if known)
- #1 ___
- #2 ___

7. Exp. date (if known)
- #1 ___
- #2 ___

8. Event reappeared after reintroduction
- #1 ☐ yes ☐ no ☐ doesn't apply
- #2 ☐ yes ☐ no ☐ doesn't apply

9. NDC # (for product problems only) – –

10. Concomitant medical products and therapy dates (exclude treatment of event)

D. Suspect medical device

1. Brand name

2. Type of device

3. Manufacturer name & address

4. Operator of device
- ☐ health professional
- ☐ lay user/patient
- ☐ other: ___

5. Expiration date (mo/day/yr)

6. model # ___
catalog # ___
serial # ___
lot # ___
other # ___

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7. If implanted, give date (mo/day/yr) DSS

8. If explanted, give date (mo/day/yr) JUL 03 2001

9. Device available for evaluation? (Do not send to FDA)
☐ yes ☐ no ☐ returned to manufacturer on ___ (mo/day/yr)

10. Concomitant medical products and therapy dates (exclude treatment of event)

[redacted]

E. Reporter (see confidentiality section on back)

1. Name, address & phone #

[redacted] PharmD
Pharmacy (119), Maryland VA Health Care
10 N Greene St, Balt MD 21201

2. Health professional? ☒ yes ☐ no

3. Occupation: Clinical Pharmacist

4. Also reported to
- ☐ manufacturer
- ☐ user facility
- ☐ distributor

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box. ☐

Mail to: MEDWATCH, 5600 Fishers Lane, Rockville, MD 20852-9787

or FAX to: 1-800-FDA-0178

FDA Form 3500 (5/93) Submission of this report does not constitute an admission that medical personnel or the product caused or contributed to the event.

JUL 03 2001

CTU 146490

MEDWATCH
Individual Safety Report

3751179-6-00-01

FOR VOLUNTARY reporting
of adverse events and product problems

Page ___ of ___

FDA Use Only
Triage unit sequence #: 146480

A. Patient information

1. Patient identifier	2. Age at time of event: / or Date of birth:	3. Sex	4. Weight
[redacted] 3538 In confidence	83	☐ female ☒ male	___ lbs or ___ kgs

B. Adverse event or product problem

1. ☒ Adverse event and/or ☐ Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)
☐ death (mo/day/yr) ___
☐ life-threatening
☐ hospitalization – initial or prolonged
☐ disability
☐ congenital anomaly
☐ required intervention to prevent permanent impairment/damage
☐ other: ___

3. Date of event (mo/day/yr): 5/31/01

4. Date of this report (mo/day/yr): 6/8/01

5. Describe event or problem

Pt on hepa and aspirin for atrial thrombus and CAD. Pt developed a GI bleed while in ICU. GI consulted, EGD: 2 duodenal ulcers which were injected with epinephrine, lansoprazole, 6 units PRBCs, hepa, aspirin D/c'ed.

6. Relevant tests/laboratory data, including dates

Hct 28 → 21
PTT 61

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JUL 03 2001

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

PVD, Dm, CHF, AFib, HTN, Prostate CA, CAD, CVA

DSS
JUL 03 2001

Device ~~Product~~ Probable

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
#1 hepa
#2 aspirin

2. Dose, frequency & route used
#1
#2 81mg QD

3. Therapy dates (if unknown, give duration) (from/to (or best estimate))
#1
#2 5/31 - 6/4/01

4. Diagnosis for use (indication)
#1 atrial thrombus
#2 CAD

5. Event abated after use stopped or dose reduced
#1 ☐ yes ☐ no ☐ doesn't apply
#2 ☐ yes ☐ no ☐ doesn't apply

6. Lot # (if known)
#1
#2

7. Exp. date (if known)
#1
#2

8. Event reappeared after reintroduction
#1 ☐ yes ☐ no ☐ doesn't apply
#2 ☐ yes ☐ no ☐ doesn't apply

9. NDC # (for product problems only)
- -

10. Concomitant medical products and therapy dates (exclude treatment of event)

D. Suspect medical device

1. Brand name

2. Type of device

3. Manufacturer name & address

4. Operator of device
☐ health professional
☐ lay user/patient
☐ other: ___

5. Expiration date (mo/day/yr)

6.
model # ___
catalog # ___
serial # MEDWATCH CTU
lot # ___
other # ___

7. If implanted, give date (mo/day/yr)

8. If explanted, give date (mo/day/yr)

9. Device available for evaluation? (Do not send to FDA)
☐ yes ☐ no ☐ returned to manufacturer on ___ (mo/day/yr)

10. Concomitant medical products and therapy dates (exclude treatment of event)

E. Reporter (see confidentiality section on back)

1. Name, address & phone: [redacted] Pharm D

2. Health professional? ☒ yes ☐ no

3. Occupation: Clinical Pharmacist

4. Also reported to
☐ manufacturer
☐ user facility
☐ distributor

5. If you do NOT want your identity disclosed to the manufacturer, place an " X " in this box. ☐

Mail to: MEDWATCH, 5600 Fishers Lane, Rockville, MD 20852-9787
or FAX to: 1-800-FDA-0178

FDA Form 3500 (6/93) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

CTU 146480

Individual Safety Report

3751181-4-00-01

THE FDA MEDICAL PRODUCT...

...VOLUNTARY reporting
...lth professionals of adverse
...nts and product problems

Page ___ of ___

FDA Use Only
Triage unit sequence # 146481

A. Patient information

1. Patient identifier: [redacted]# 3940 In confidence
2. Age at time of event: 40 or Date of birth:
3. Sex: ☐ female ☒ male
4. Weight: ___ lbs or ___ kgs

B. Adverse event or product problem

1. ☒ Adverse event and/or ☐ Product problem (e.g., defects/malfunctions)
2. Outcomes attributed to adverse event (check all that apply)
   - ☐ death ___ (mo/day/yr)
   - ☐ life-threatening
   - ☐ hospitalization – initial or prolonged
   - ☐ disability
   - ☐ congenital anomaly
   - ☐ required intervention to prevent permanent impairment/damage
   - ☐ other: ___
3. Date of event (mo/day/yr): 6/5/01
4. Date of this report (mo/day/yr): 6/6/01
5. Describe event or problem

Pt c̄ tarry stools for 2 days PTA. NG lavage neg. Anoscopy ⊕ blood. ICU admission, EGD: Dieulafoy's lesion in duodenum treated with epinephrine and heat probe. Received 8 units PRBCs, amoxicillin, lansoprazole, Clarithromycin. Bleeding sea, colonoscopy ⊖. Surgery consulted.

6. Relevant tests/laboratory data, including dates

Hct 35 → 30

MEDWATCH
JUL 03 2001

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

GI bleed, MVA, EtOH

DSS
JUL 03 2001

severe probable

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
   - #1 ibuprofen ~~+ EtOH~~
   - #2 aspirin
2. Dose, frequency & route used
   - #1
   - #2
3. Therapy dates (if unknown, give duration) from/to (or best estimate)
   - #1
   - #2
4. Diagnosis for use (indication)
   - #1 knee pain
   - #2
5. Event abated after use stopped or dose reduced
   - #1 ☐ yes ☐ no ☐ doesn't apply
   - #2 ☐ yes ☐ no ☐ doesn't apply
6. Lot # (if known)
   - #1
   - #2
7. Exp. date (if known)
   - #1
   - #2
8. Event reappeared after reintroduction
   - #1 ☐ yes ☐ no ☐ doesn't apply
   - #2 ☐ yes ☐ no ☐ doesn't apply
9. NDC # (for product problems only)
10. Concomitant medical products and therapy dates (exclude treatment of event)

D. Suspect medical device

1. Brand name
2. Type of device
3. Manufacturer name & address
4. Operator of device
   - ☐ health professional
   - ☐ lay user/patient
   - ☐ other:
5. Expiration date (mo/day/yr)
6. model #
   catalog #
   serial #
   lot #
   other #

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JUL 03 2001
MEDWATCH CTU

7. If implanted, give date (mo/day/yr)
8. If explanted, give date (mo/day/yr)
9. Device available for evaluation? (Do not send to FDA) ☐ yes ☐ no ☐ returned to manufacturer on ___ (mo/day/yr)
10. Concomitant medical products and therapy dates (exclude treatment of event)

[redacted]

E. Reporter (see confidentiality section on back)

1. Name, address & phone #
[redacted] PharmD Pharmacy
Maryland VA Health Care System
10 N Greene St Balt MD 21201
2. Health professional? ☒ yes ☐ no
3. Occupation: Clinical Pharmacist
4. Also reported to
   - ☐ manufacturer
   - ☐ user facility
   - ☐ distributor
5. If you do NOT want your identity disclosed to the manufacturer, place an " X " in this box. ☐

FDA
Mail to: MEDWATCH
5600 Fishers Lane
Rockville, MD 20852-9787
or FAX to: 1-800-FDA-0178

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

CTU 146481

Individual Safety Report

3751183-8-00-01

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

...oluntary reporting
...lth professionals of adverse
...ts and product problems

FDA Use Only
Triage unit sequence # 146482

A. Patient information

1. Patient identifier	2. Age at time of event: / or Date of birth:	3. Sex	4. Weight
G# 3957 [redacted] In confidence	70	☐ female ☒ male	___ lbs or ___ kgs

B. Adverse event or product problem

1. ☒ Adverse event and/or ☐ Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)
- ☐ death ___ (mo/day/yr)
- ☐ life-threatening
- ☒ hospitalization – initial or prolonged
- ☐ disability
- ☐ congenital anomaly
- ☐ required intervention to prevent permanent impairment/damage
- ☐ other: ___

3. Date of event (mo/day/yr): 6/22/01

4. Date of this report (mo/day/yr): 6/25/01

5. Describe event or problem

Pt admitted for hematochezia. Had EGD/colonoscopy one year ago which showed diverticuli. This EGD neg for source of upper GI bleed Angiogram (-). ~~Bleeding Scan~~ Tagged RBC (+) Pt received 9 units PRBCs and hemicolectomy, ranitidine.

6. Relevant tests/laboratory data, including dates

Hct 35 → 26.1

MEDWATCH CTU
JUL 03 2001

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

CHF, CAD, DM, CVA, PVD

DSG
JUL 03 2001

severe probable

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
- #1 aspirin
- #2

2. Dose, frequency & route used
- #1
- #2

3. Therapy dates (if unknown, give duration) from/to (or best estimate)
- #1
- #2

4. Diagnosis for use (indication)
- #1 CVA, CAD
- #2

5. Event abated after use stopped or dose reduced
- #1 ☐ yes ☐ no ☐ doesn't apply
- #2 ☐ yes ☐ no ☐ doesn't apply

6. Lot # (if known)
- #1
- #2

7. Exp. date (if known)
- #1
- #2

8. Event reappeared after reintroduction
- #1 ☐ yes ☐ no ☐ doesn't apply
- #2 ☐ yes ☐ no ☐ doesn't apply

9. NDC # (for product problems only)
- -
- -

10. Concomitant medical products and therapy dates (exclude treatment of event)

D. Suspect medical device

1. Brand name

2. Type of device

3. Manufacturer name & address

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4. Operator of device
- ☐ health professional
- ☐ lay user/patient
- ☐ other: ___

5. Expiration date (mo/day/yr)

6.
- model # ___
- catalog # ___
- serial # ___
- lot # ___
- other # ___

7. If implanted, give date (mo/day/yr)

8. If explanted, give date (mo/day/yr)

9. Device available for evaluation? (Do not send to FDA)
☐ yes ☐ no ☐ returned to manufacturer on: ___ (mo/day/yr)

10. Concomitant medical products and therapy dates (exclude treatment of event)

[redacted]

E. Reporter (see confidentiality section on back)

1. Name, address & phone #: [redacted] Pharm D

2. Health professional? ☒ yes ☐ no

3. Occupation: Clinical Pharmacist

4. Also reported to
- ☐ manufacturer
- ☐ user facility
- ☐ distributor

5. If you do NOT want your identity disclosed to the manufacturer, place an " X " in this box. ☐

Mail to: MEDWATCH, 5600 Fishers Lane, Rockville, MD 20852-9787
or FAX to: 1-800-FDA-0178

FDA Form 3500 (6/03) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

CTU 146482

Individual Safety Report ents and product problems

3751185-1-00-01

Page ___ of ___

146484

A. Patient Identifier

Patient identifier	Age at time of event: / Date of birth:	Sex	Weight
#6256 3A In confidence	83	☐ female ☒ male	___ lbs or ___ kgs

B. Adverse event or product problem

1. ☒ Adverse event and/or ☐ Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)
- ☐ death (mo/day/yr)
- ☐ life-threatening
- ☐ hospitalization – initial or prolonged
- ☐ disability
- ☐ congenital anomaly
- ☐ required intervention to prevent permanent impairment/damage
- ☐ other:

3. Date of event (mo/day/yr): 5/19/01

4. Date of this report (mo/day/yr): 5/21/01

5. Describe event or problem

Pt admitted for symptomatic anemia associated with CP. Given SL NTG, 2 units PRBCs. Continued lansoprazole, aspirin and warfarin. Plan for enteroscopy by GI later. Suspect GI source of bleed c hemo ⊕ stool.

6. Relevant tests/laboratory data, including dates

Hct 30 → 23.7

INR 2.31

MEDWATCH JUL 03 2001

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

CAD c MI, CHF, DM, anemia, AFib, CVA, seizure

DSS JUL 03 2001

Severe Possible

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
- #1 warfarin
- #2 aspirin

2. Dose, frequency & route used
- #1 5mg po QD
- #2 325mg po QD

3. Therapy dates (if unknown, give duration) from/to (or best estimate)
- #1
- #2

4. Diagnosis for use (indication)
- #1 AFib c CVA
- #2 CAD/MI

5. Event abated after use stopped or dose reduced
- #1 ☐ yes ☐ no ☐ doesn't apply
- #2 ☐ yes ☐ no ☐ doesn't apply

6. Lot # (if known)
- #1
- #2

7. Exp. date (if known)
- #1
- #2

8. Event reappeared after reintroduction
- #1 ☐ yes ☐ no ☐ doesn't apply
- #2 ☐ yes ☐ no ☐ doesn't apply

9. NDC # (for product problems only)

10. Concomitant medical products and therapy dates (exclude treatment of event)

D. Suspect medical device

1. Brand name

2. Type of device

3. Manufacturer name & address

4. Operator of device
- ☐ health professional
- ☐ lay user/patient
- ☐ other:

5. Expiration date (mo/day/yr)

6.
- model # RECEIVED
- catalog # JUL 03 2001
- serial #
- lot # MEDWATCH CTU
- other #

7. If implanted, give date (mo/day/yr)

8. If explanted, give date (mo/day/yr)

9. Device available for evaluation? (Do not send to FDA)
☐ yes ☐ no ☐ returned to manufacturer on ___ (mo/day/yr)

10. Concomitant medical products and therapy dates (exclude treatment of event)

E. Reporter (see confidentiality section on back)

1. Name [redacted]

2. Health professional? ☒ yes ☐ no

3. Occupation: Clinical Pharmacist

4. Also reported to
- ☐ manufacturer
- ☐ user facility
- ☐ distributor

5. If you do NOT want your identity disclosed to the manufacturer, place an " X " in this box. ☐

Mail to: MEDWATCH, 5600 Fishers Lane, Rockville, MD 20852-9787 or FAX to: 1-800-FDA-0178

FDA Form 3500 (5/93) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

CTU 146484

Individual Safety Report

3754425-8-00-01

MEDWATCH

FDA MEDICAL PRODUCTS REPORTING PROGRAM

VOLUNTARY reporting by health professionals of adverse events and product problems

Page ___ of ___ CORRN

Form Approved: OMB No. 0910-0291 Expires: 12/31/94
See OMB statement on reverse

FDA Use Only (MB)

Triage unit sequence # 146776

A. Patient information

Patient identifier: 1292 In confidence

2. Age at time of event: 50 or Date of birth:

3. Sex: ☐ female ☒ male

4. Weight: ___ lbs or ___ kgs

B. Adverse event or product problem

☒ Adverse event and/or ☐ Product problem (e.g., defects/malfunctions)

Outcomes attributed to adverse event (check all that apply)

☐ death ___ (mo/day/yr)
☐ life-threatening
☒ hospitalization – initial or prolonged
☐ disability
☐ congenital anomaly
☐ required intervention to prevent permanent impairment/damage
☐ other: ___

Date of event (mo/day/yr): 4/2/01

4. Date of this report (mo/day/yr):

Describe event or problem

HCT ↓ from 43 to 28
abdominal pain, some melena. weakness
"gastric ulcers consistent with NSAID use."

5 Relevant tests/laboratory data, including dates

Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

DSS

JUL 10 2001

CTV146776

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
#1 Indomethacin
#2 ASA (325mg)

2. Dose, frequency & route used
#1 50mg tid
#2 5 po qd

3. Therapy dates (if unknown, give duration) from/to (or best estimate)
#1 1/23/01 → 4/02/01
#2 → 4/02/01

4. Diagnosis for use (indication)
#1 arthritis
#2

5. Event abated after use stopped or dose reduced
#1 ☐ yes ☐ no ☐ doesn't apply
#2 ☐ yes ☐ no ☐ doesn't apply

6. Lot # (if known)
#1
#2

7. Exp. date (if known)
#1
#2

8. Event reappeared after reintroduction
#1 ☐ yes ☐ no ☐ doesn't apply
#2 ☐ yes ☐ no ☐ doesn't apply

9. NDC # (for product problems only)
– –

10. Concomitant medical products and therapy dates (exclude treatment of event)

D. Suspect medical device

1. Brand name

2. Type of device

3. Manufacturer name & address

RECEIVED
JUL 09 2001
MEDWATCH CTU

4. Operator of device
☐ health professional
☐ lay user/patient
☐ other: ___

5. Expiration date (mo/day/yr)

6.
model # ___
catalog # ___
serial # ___
lot # ___
other # ___

7. If implanted, give date (mo/day/yr)

8. If explanted, give date (mo/day/yr)

9. Device available for evaluation? (Do not send to FDA)
☐ yes ☐ no ☐ returned to manufacturer on ___ (mo/day/yr)

10. Concomitant medical products and therapy dates (exclude treatment of event)

E. Reporter (see confidentiality section on back)

1. Name, address & phone #
[redacted]
MINTER BLVD.
SAN ANTONIO, TX 78284

2. Health professional? ☒ yes ☐ no

3. Occupation: Pharm D

4. Also reported to
☐ manufacturer
☐ user facility
☐ distributor

5. If you do NOT want your identity disclosed to the manufacturer, place an " X " in this box. ☒

...medical personnel or the product caused or contributed to the event.

Mail to: MEDWATCH 5600 Fishers Lane Rockville, MD 20852-9787

or FAX to: 1-800-FDA-0178

JUL-10-'01 10:56 T- #058-01

Individual Safety Report

3756913-7-00-01

VOLUNTARY reporting
ealth professionals of adverse
ents and product problems

Page 1 of 2 CBL

Form Approved: OMB No. 0910-0291 Expires: 12/31/01
See OMB statement on reverse

FDA Use Only (MB)
Triage unit sequence #: 146884

PLEASE TYPE OR USE BLACK INK

A. Patient information

1. Patient identifier	2. Age at time of event: / or Date of birth:	3. Sex	4. Weight
1281816 In confidence	61	☐ female ☑ male	215 lbs or ___ kgs

B. Adverse event or product problem

1. ☑ Adverse event and/or ☐ Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)
- ☐ death ___ (mo/day/yr)
- ☐ life-threatening
- ☑ hospitalization – initial or prolonged
- ☐ disability
- ☐ congenital anomaly
- ☐ required intervention to prevent permanent impairment/damage
- ☐ other: ___

3. Date of event (mo/day/yr): 3-25-01

4. Date of this report (mo/day/yr): 6-8-01

5. Describe event or problem

3-23-01 Patient received thrombolytic therapy at other hospital for AMI. Chest pain 7 7min p infusion. Patient transfered AM 3-24-01 for cardiac cath.
3-25-01 passed bright red blood per rectum & other symptoms, (& anemia) GI consult obtained
3-29-01 Anemia + Bleed Under control - proceeded w/ cath

6. Relevant tests/laboratory data, including dates

3-25-01 HCT 33 HgB 11.1 APTT 52
3-26-01 HCT 29 HgB 9.6 APTT 41
3-28-01 HCT 27 HgB 9.1 APTT 55

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

3-23-01 acute AMI w/ V. fib
no prior cardhx
3-22-01 polypectomy
hypertension enalapril

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known) (continued see p 7)
- #1 Heparin
- #2 Heparin

2. Dose, frequency & route used
- #1 4000 unit bolus 1160 units/hr infus
- #2 1300 units/hr

3. Therapy dates (if unknown, give duration) from/to (or best estimate)
- #1 3-23-01 1818 - 3-24 1115
- #2 3-24 1115 - 3-25 1800

4. Diagnosis for use (indication)
- #1 acute AMI
- #2 acute AMI

5. Event abated after use stopped or dose reduced
- #1 ☑ yes ☐ no ☐ doesn't apply
- #2 ☑ yes ☐ no ☐ doesn't apply

6. Lot # (if known)
- #1
- #2

7. Exp. date (if known)
- #1
- #2

8. Event reappeared after reintroduction
- #1 ☐ yes ☑ no ☐ doesn't apply
- #2 ☐ yes ☑ no ☐ doesn't apply

9. NDC # (for product problems only)
- –
- –

10. Concomitant medical products and therapy dates (exclude treatment of event)

D. Suspect medical device

1. Brand name

2. Type of device

3. Manufacturer name & address

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4. Operator of device
- ☐ health professional
- ☐ lay user/patient
- ☐ other: ___

5. Expiration date (mo/day/yr)

6.
- model # ___
- catalog # ___
- serial # ___
- lot # ___
- other # ___

7. If implanted, give date (mo/day/yr)

8. If explanted, give date (mo/day/yr)

9. Device available for evaluation? (Do not send to FDA)
☐ yes DSS ☐ no ☐ returned to manufacturer on ___ (mo/day/yr)

10. Concomitant medical products and therapy dates (exclude treatment of event)
JUL 11 2001 DSS
11 2001

E. Reporter (see confidentiality section on back)

1. Name, address & phone #
[redacted]

2. Health professional? ☑ yes ☐ no

3. Occupation: Rph

4. Also reported to
- ☐ manufacturer
- ☑ user facility
- ☐ distributor

5. If you do NOT want your identity disclosed to the manufacturer, place an " X " in this box. ☒

FDA Mail to: MEDWATCH
5600 Fishers Lane
Rockville, MD 20852-9787

MEDWATCH

FDA Form 3500 (5/93) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

JUL 10 2001

CTU 146884

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JUL-10-'01 10:57 T- #058-02

MEDWATCH

Individual Safety Report

3756913-7-00-02

For VOLUNTARY reporting
lth professionals of adverse
ıts and product problems

Form Approved: OMB No. 0910-0291 Expires: 12/31/9
See OMB statement on reverse

FDA Use Only (MB)

Triage unit sequence #: 146884

A. Patient information

1. Patient identifier	2. Age at time of event: / or Date of birth:	3. Sex	4. Weight
1281816 In confidence	61	☐ female ☒ male	215 lbs or ___ kgs

B. Adverse event or product problem

1. ☐ Adverse event and/or ☐ Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)
- ☐ death ___ (mo/day/yr)
- ☒ life-threatening
- ☒ hospitalization – initial or prolonged
- ☐ disability
- ☐ congenital anomaly
- ☐ required intervention to prevent permanent impairment/damage
- ☐ other: ___

3. Date of event (mo/day/yr): 3-25-01

4. Date of this report (mo/day/yr): 6-8-01

5. Describe event or problem

6. Relevant tests/laboratory data, including dates

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JUL 10 2001
MEDWATCH CTU

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
#1 "TNK"
#2 ~~[illegible]~~ [illegible] aspirin 325mg

2. Dose, frequency & route used
#1 90mg IVP over 5 seconds
#2 325mg po qd

3. Therapy dates (if unknown, give duration) (from/to (or best estimate))
#1 3-23 1808
#2 3-24 – 3-30 →

4. Diagnosis for use (indication)
#1 acute AMI
#2

5. Event abated after use stopped or dose reduced
#1 ☒ yes ☐ no ☐ doesn't apply
#2 ☐ yes ☐ no ☐ doesn't apply

6. Lot # (if known)
#1
#2

7. Exp. date (if known)
#1
#2

8. Event reappeared after reintroduction
#1 ☐ yes ☐ no ☒ doesn't apply
#2 ☐ yes ☐ no ☒ doesn't apply

9. NDC # (for product problems only)
– –

10. Concomitant medical products and therapy dates (exclude treatment of event)
heparin
aspirin
TNK
atenolol
lisinopril
lipitor

D. Suspect medical device

1. Brand name

2. Type of device

3. Manufacturer name & address

4. Operator of device
- ☐ health professional
- ☐ lay user/patient
- ☐ other: ___

5. Expiration date (mo/day/yr)

6.
model # ___
catalog # ___
serial # ___
lot # ___
other # ___

7. If implanted, give date (mo/day/yr)

8. If explanted, give date (mo/day/yr)

9. Device available for evaluation? (Do not return to FDA)
☐ yes ☐ no ☐ returned to manufacturer on ___ (mo/day/yr)

DSS
JUL 11 2001

10. Concomitant medical products and therapy dates (exclude treatment of event)

E. Reporter (see confidentiality section on back)

1. Name, address & phone #

2. Health professional? ☐ yes ☐ no

3. Occupation

4. Also reported to
- ☐ manufacturer
- ☐ user facility
- ☐ distributor

5. If you do NOT want your identity disclosed to the manufacturer, place an " X " in this box. ☒

PLEASE TYPE OR USE BLACK INK

FDA

Mail to: MEDWATCH
5600 Fishers Lane
Rockville, MD 20852-9787

or FAX to:
1-800-FDA-0178

FDA Form 3500 (6/93)

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

146884

CERT# 0794 7822

MedWatch

The FDA Medical Products Reporting Program

Merck Human Health Division

For use by user-facilities, distributors and manufacturers for MANDATORY reporting

NO ATTACHMENT

Merck Facsimile of FDA Form 3500A
Approved by FDA (10/21/93)

Mfr report #	WAES 01062374
UF/Dist report #	
	FDA Use Only

A. Patient information

1. Patient identifier	2. Age at time of event:	3. Sex	4. Weight
[redacted] in confidence	or 80 years Date of Birth: [redacted]	☐ Female ☒ Male	Unk

B. Adverse event or product problem

1. ☒ Adverse event and / or ☐ Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

- ☐ death _____ (mo/day/yr)
- ☒ life-threatening
- ☒ hospitalization-initial or prolonged
- ☐ disability
- ☐ congenital anomaly
- ☐ required intervention to prevent permanent impairment/damage
- ☒ other: important medical

3. Date of event (mo/day/yr)	4. Date of this report (mo/day/yr)
06/24/01	07/17/01

5. Describe event or problem

This is in follow-up to report(s) previously submitted on 7 5 01

Information has been received from a physician and his office nurse concerning a debilitated 80 year old male nursing home patient with contact dermatitis, a hip contusion, pneumonia, and no past medical history of gastrointestinal complaints who on 15-MAR-2001, was placed on therapy with rofecoxib, 25 mg tablet (previously reported as 12.5 mg by the physician), once a day for the treatment of arthritis pain in his shoulder. Concomitant therapy included aspirin, 81 mg daily (previously reported as 325 mg daily by the physician) (duration and indication not reported) (secondary suspect). Other concomitant therapy included atenolol and cephalexin (KEFLEX) . On 24-JUN-2001, the patient developed a severe gastrointestinal (GI) bleed secondary to a duodenal ulcer and was hospitalized. On 25-JUN-2001, therapy with rofecoxib and aspirin was discontinued. The GI bleed required four units of blood. The patient subsequently completely recovered and after four days was

(Continued on Additional Page)

6. Relevant tests/laboratory data, including dates

Unknown

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

CONCURRENT CONDITIONS: contact dermatitis; contusion; debility; pneumonia

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)

#1 TAB VIOXX 25 mg

#2 aspirin 81 mg

2. Dose, frequency & route used	3. Therapy dates (from/to) (if unknown, give duration)
#1 25 mg/DAILY/PO	#1 03/16/01 - 06/25/01
#2 81 mg/DAILY/PO	#2 Unk - 06/25/01

4. Diagnosis for use (indication)	5. Event abated after use stopped or dose reduced.	yes	no	N/A	unk
#1 arthritis pain	#1	☒	☐	☐	☐
#2 Unknown	#2	☒	☐	☐	☐

6. Lot # (if known)	7. Exp date (if known)
#1	#1
#2	#2

8. Event reappeared after reintroduction.

	yes	no	N/A	unk
#1	☐	☐	☐	☒
#2	☐	☐	☐	☒

9. NDC # - for product problems only (if known)

Unknown

10. Concomitant medical products and therapy dates (exclusion treatment of event)

KEFLEX Unk -Unk

atenolol Unk -Unk

G. All manufacturers

1. Contact office - name/address

Merck Human Health Division
Merck & Co., Inc.
P.O. Box 4
West Point, PA 19486-0004

ATTN: Worldwide Product Safety

2. Phone Number: (610)397-2416

3. Report source (check all that apply)

- ☐ foreign
- ☐ study
- ☐ literature
- ☐ consumer
- ☒ health professional
- ☐ user facility
- ☒ company representative
- ☐ distributor
- ☐ other:

4. Date received by manufacturer (mo/day/yr): 07/10/01

5. (A)NDA # 21042
IND #
PLA #
pre-1938 ☐ yes
OTC product ☐ yes

6. If IND, protocol #

7. Type of report
☐ 5-day ☒ 15-day
☐ 10-day ☐ periodic
☐ initial ☒ Follow-up# 1

9. Mfr. report number: WAES 01062374

8. Adverse event term(s)

HEMORRHAGIC DUODENAL ULCER

E. Initial reporter

1. Name, address & phone #

[redacted] AVENUE [redacted]

[redacted]

DSS

JUL 20 2001

2. Health professional?	3. Occupation	4. Initial reporter also sent report to FDA.
☒ YES ☐ NO	M.D.	☐ yes ☐ no ☒ unk

Submission of a report does not constitute an admission that FDA, manufacturer, distributor, or

3762068-5-00-01

JUL 19 2001

B. Adverse event or product problem

5. Describe event or problem

discharged back to the nursing home. According to the nurse, the GI bleed was thought to be related to therapy with rofecoxib and aspirin.

The GI bleed secondary to a duodenal ulcer was considered to be immediately life threatening and an other important medical event. No further information is available.

DSS

CERT# 0794 7822

MedWatch

The FDA Medical Products Reporting Program

Merck Human Health Division

For use by user-facilities, distributors and manufacturers for MANDATORY reporting

Merck Facsimile of FDA Form 3500A
Approved by FDA (10/21/93)

Mfr report # WAES 01052780

UF/Dist report #

FDA Use Only

NO ATTACHMENT

50333133

A. Patient information

1. Patient identifier	2. Age at time of event:	3. Sex	4. Weight
[redacted]	or 63 years	☐ Female	114 lbs
In confidence	Date of Birth:	☒ Male	

B. Adverse event or product problem

1 ☒ Adverse event and / or ☐ Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

- ☐ death _____ (mo/day/yr)
- ☐ life-threatening
- ☒ hospitalization-initial or prolonged
- ☐ disability
- ☐ congenital anomaly
- ☐ required intervention to prevent permanent impairment/damage
- ☒ other: important medical

3. Date of event (mo/day/yr): 02/13/01

4. Date of this report (mo/day/yr): 07/17/01

5. Describe event or problem

This is in follow-up to report(s) previously submitted on 6-6-01

Information has been received for a direct report from the FDA concerning a 63 year old male patient with gastroesophageal reflux symptoms who consumes one or two alcoholic drinks per day and smokes one pack per day, and who, in approximately December 2000, was placed on therapy with rofecoxib, 50 mg tablet, once a day for the treatment of a herniated C4-C5 disc. Concomitant therapy included aspirin, 325 mg, once daily (duration and indication not reported). On 13-FEB-2001 the patient developed blood in his stool and dark, black stools. On 14-FEB-2001 the patient was admitted to the hospital. On approximately 14-FEB-2001, after approximately two months of therapy, rofecoxib was discontinued. The patient also reported epigastric pain after meals and when lying down. Laboratory test results on 14-FEB-2001 revealed International Normalized Ratio (INR) was 0.95, partial thromboplastin time (PTT) was 27.7, hemoglobin was 16.5, mean corpuscular volume (MCV) was 102.5, mean corpuscular

(Continued on Additional Page)

6. Relevant tests/laboratory data, including dates

Refer to Additional Page

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

CONCURRENT CONDITIONS: alcohol consumption; chronic obstructive pulmonary disease; gastroesophageal reflux disease; rheumatic fever; smoking

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)

#1 TAB VIOXX 50 mg

#2 TAB aspirin 325 mg

2. Dose, frequency & route used	3. Therapy dates (from/to) (if unknown, give duration)
#1 50 mg/DAILY/PO	#1 01/14?/01 - 02/14?/01
#2 325 mg/DAILY/PO	#2 Unk - 02/16/01

4. Diagnosis for use (indication)

#1 herniated disc, pain

#2 rheumatic fever

5. Event abated after use stopped or dose reduced

	yes	no	N/A	unk
#1	☒	☐	☐	☐
#2	☐	☐	☐	☒

6. Lot # (if known): #1 _____ #2 _____

7. Exp date (if known): #1 _____ #2 _____

8. Event reappeared after reintroduction

	yes	no	N/A	unk
#1	☐	☐	☒	☐
#2	☐	☐	☐	☒

9. NDC # - for product problems only (if known): Unknown

10. Concomitant medical products and therapy dates (exclude treatment of event)

INDOCIN (INDOMETHACIN) Unk - Unk

G. All manufacturers

1. Contact office - name/address

Merck Human Health Division
Merck & Co., Inc.
P.O. Box 4
West Point, PA 19486-0004

ATTN: Worldwide Product Safety

2. Phone Number: (610)397-2416

3. Report source (check all that apply)

- ☐ foreign
- ☐ study
- ☐ literature
- ☐ consumer
- ☒ health professional
- ☐ user facility
- ☐ company representative
- ☐ distributor
- ☒ other: CTU 141188

4. Date received by manufacturer (mo/day/yr): 07/11/01

5. (A)NDA # 21042 IND # _____ PLA # _____ pre-1938 ☐ yes OTC product: ☐ yes

6. If IND, protocol #

7. Type of report

- ☐ 5-day ☒ 15-day
- ☐ 10-day ☐ periodic
- ☐ initial ☒ Follow-up# 1

9. Mfr. report number: WAES 01052780

8. Adverse event term(s)

DUODENAL ULCER; BLEEDING TIME INCREASED; EROSIVE ESOPHAGITIS; GASTROINTESTINAL BLEEDING; GASTROINTESTINAL ULCER

E. Initial reporter

1. Name, address & phone #

[redacted] AVENUE [redacted] MEDICAL CENTER [redacted]

DSS

JUL 20 200

2. Health professional?	3. Occupation	4. Initial reporter also sent report to FDA
☒ YES ☐ NO	Pharm.D.	☐ yes ☐ no ☒ unk

Submission of a report does not constitute an admission that

FD [illegible]

3762070-3-00-01

JUL 19 2001

B. Adverse event or product problem

5. Describe event or problem

hemoglobin (MCH) was 34, platelet count was 326000, and bleeding time was greater than 15 minutes. An esophagogastroduodenoscopy (EGD) was performed which revealed grade 4 esophagitis, duodenal ulcers, and one post-duodenal ulcer. The patient was placed on therapy with unspecified proton pump inhibitors. On 16-FEB-2001 hemoglobin was stable at 11.6 and the patient was discharged from the hospital. The report indicated that the patient was to remain on "life long" therapy with proton pump inhibitors, but indicated that the symptoms abated following discontinuation of rofecoxib. Aspirin was considered a secondary suspect medication.

Additional information has been received from the pharmacist who originally reported the information concerning the 63 year old, white, male patient. Additional concurrent conditions included chronic obstructive pulmonary disease and concomitant therapy included indomethacin (MSD). The pharmacist clarified that on aproximately 14-JAN-2001 the patient was placed on therapy with rofecoxib, 50 mg tablet, once daily for the treatment of pain. Aspirin therapy was for the treatment of rheumatic fever. On 14-FEB-2001 the patient presented to the emergency room with red blood in his stool and dark black stools since the day prior. The patient also complained of vomiting dark, bloody chunks on the morning of 14-FEB-2001. Aspirin therapy was discontinued on 16-FEB-2001. Additional follow up was received from a completed questionaire. The source of the bleeding was identified as the grade IV/erosive esopnagitis and the duodenal ulcer. No tests were completed for Helicobacter Pylori.

The reporting pharmacist considered the gastrointestinal bleeding, duodenal ulcer, gastrointestinal ulcer, and erosive esophagitis to be Other Important Medical Events. Additional information is not expected.

This report was filed with the FDA. The CTU number is 141198.

6. Relevant tests/laboratory data, including dates

DIAGNOSTIC TEST

Tests	Date	Value	Unit	Normal Range
esophagogastroduodenoscopy	02/14/01			
Comment: grade 4 esopnagitis, duodenal ulcers, one post-duodenal ulcer				

LABORATORY RESULTS

Tests	Date	Value	Unit	Normal Range
APTT	02/14/01	27.7		
INR	02/14/01	0.95		
hemoglobin	02/14/01	16.5		
platelet count	02/14/01	326000		
bleeding time	02/14/01	>15	min.	
mean corpuscular hemoglobin	02/14/01	34		
mean corpuscular volume	02/14/01	102.5		
hemoglobin	02/18/01	11.6		

Individual Safety Report

3766762-1-00-01

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

VOLUNTARY reporting
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Page 1 of 1

Form Approved: OMB No. 0910-0291 Expires:12/31/94
See OMB statement on reverse

FDA Use Only

Triage unit sequence # 157958

Patient information

1. ent identifier	2. Age at time of event:	3. Sex	4. Weight
[redacted]5575 In confidence	or ____ Date of birth: [redacted]	☑ female ☐ male	____ lbs or ____ kgs

B. Adverse event or product problem

1. ☑ Adverse event and/or ☐ Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

☐ death ____ (mo/day/yr)
☐ life-threatening
☑ hospitalization – initial or prolonged
☐ disability
☐ congenital anomaly
☑ required intervention to prevent permanent impairment/damage
☐ other: ____

3. Date of event (mo/day/yr) 6/11/01

4. Date of this report (mo/day/yr) 6/13/01

5. Describe event or problem

aoe_id adr_desc

5575 92 YOF presented to ED with CP on exertion, SOB, lightheadedness, and brief syncopal episode. Pt seen by LMD on 6/8 for DOE. Hgb decr from 10.2 (5/19) to 7.9. Pt developed black stool a few days PTA. Pt denied N/V/BRBPR/abd pain. On adm, Hgb=5.9, VS: BP 92/37, HR=110, stool= heme (+) and black. Pt denies ETOH use but (+) NSAID (aspirin) use for thrombus prophylaxis. Pt with anemia secondary to GI bleed and probable MI secondary to ischemia. Pt to have endoscopy. ASA held. Pt given IVF and 2 units PRBCs. NG lavage (-). On 6/13, pt given 2 additional units PRBCs, stool no longer black, Hgb=10.9. No CP or abd pain. Preliminary BE revealed sigmoid diverticulosis.

ade id

Relevant tests/laboratory data, including dates

DSS
JUL 30 2001

Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

PMH: CABG, CHF, HTN
BL hip replacement
GERD

Allergies: PCN

CTV#47958

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
#1 ASA
#2

2. Dose, frequency & route used
#1 325 mg PO qd
#2

3. Therapy dates (if unknown, give duration) (from/to (or best estimate))
#1 PTA
#2

4. Diagnosis for use (indication)
#1 prophylaxis
#2

5. Event abated after use stopped or dose reduced
#1 ☑ yes ☐ no ☐ doesn't apply
#2 ☐ yes ☐ no ☐ doesn't apply

6. Lot # (if known)
#1
#2

7. Exp. date (if known)
#1
#2

8. Event reappeared after reintroduction
#1 ☐ yes ☐ no ☐ doesn't apply
#2 ☐ yes ☐ no ☐ doesn't apply

9. NDC # (for product problems only)
- -

10. Concomitant medical products and therapy dates (exclude treatment of event)
metoprolol ranitidine
furosemide
lisinopril
isosorbide mononitrate

D. Suspect medical device

1. Brand name

2. Type of device

3. Manufacturer name & address

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MEDWATCH CTU

4. Operator of device
☐ health professional
☐ lay user/patient
☐ other: ____

5. Expiration date (mo/day/yr)

6. model # ____
catalog # ____
serial # ____
lot # ____
other # ____

7. If implanted, give date (mo/day/yr)

8. If explanted, give date (mo/day/yr)

9. Device available for evaluation? (Do not send to FDA)
☐ yes ☐ no ☐ returned to manufacturer on ____ (mo/day/yr)

10. Concomitant medical products and therapy dates (exclude treatment of event)

E. Reporter (see confidentiality section on back)

1. Name, address & phone #
[redacted], PharmD
Hospital [redacted]
Department of Pharmacy Services
[redacted] Street [redacted]
[redacted]
Phone: [redacted]

2. Health professional? ■ yes ☐ no

3. Occupation: Pharmacist

4. Also reported to
☐ manufacturer
■ user facility
☐ distributor

5. If you do NOT want your identity disclosed to the manufacturer, place an " X " in this box. ■

Mail to: MEDWATCH
5600 Fishers Lane
Rockville, MD 20852-9787

or FAX to:
1-800-FDA-0178

FDA

FORM FDA 3500 (5/93) Submission of a report does not constitute an admission that

Individual Safety Report

3767642-8-00-01

)LUNTARY reporting
h professionals of adverse
s and product problems
Internet Submission - Page 1

Form Approved: OMB No. 0910-0291 Expires: 04/3003
See OMB statement on reverse

FDA Use Only
Triage unit sequence # 148008

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

A. Patient information

1. Patient identifier [redacted] In confidence
2. Age at time of event: or Date of birth:
3. Sex ☐ female ☐ male
4. Weight ____ lbs or ____ kgs

B. Adverse event or product problem

1. ☑ Adverse event and/or ☐ Product problem (e.g., defects/malfunctions)
2. Outcomes attributed to adverse event (check all that apply)
   - ☐ death (mm/dd/yyyy)
   - ☐ life-threatening
   - ☑ hospitalization – initial or prolonged
   - ☐ disability
   - ☐ congenital anomaly
   - ☐ required intervention to prevent permanent impairment/damage
   - ☐ other:
3. Date of event (mm/dd/yyyy): 03/19/2001
4. Date of this report (mm/dd/yyyy): 07/28/2001
5. Describe event or problem:

GI bleed

6. Relevant tests/laboratory data, including dates:

hct = 22 hgb = 6.8

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

asa po 10/day x many years

MEDWATCH

JUL 30 2001

CTU148008

C. Suspect medication(s)

1. Name (Product Name) / (Labeled Strength) / (Mfr/Labeler)
   - #1 asa / ASPIRIN /
   - #2
2. Dose/Frequency/Route used
   - #1
   - #2
3. Therapy dates (if unknown, give duration) From / To (or best estimate)
   - #1
   - #2
4. Diagnosis for use (separate indications with commas)
   - #1
   - #2
5. Event abated after use stopped or dose reduced
   - #1 ☐ yes ☐ no ☑ doesn't apply
   - #2 ☐ yes ☐ no ☐ doesn't apply
6. Lot # (if known)
   - #1
   - #2
7. Exp. date (if known)
   - #1
   - #2
8. Event reappeared after reintroduction
   - #1 ☐ yes ☐ no ☐ doesn't apply
   - #2 ☐ yes ☐ no ☐ doesn't apply
9. NDC # (for product problems only) – –
10. Concomitant medical products and therapy dates (exclude treatment of event)

D. Suspect medical device

1. Brand name
2. Type of device
3. Manufacturer name & address

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JUL 30 2001
MEDWATCH CTU

4. Operator of device
   - ☐ health professional
   - ☐ lay user/patient
   - ☐ other:
5. Expiration date (mm/dd/yyyy)
6. model #
   catalog #
   serial #
   lot #
   other #
7. If implanted, give date (mm/dd/yyyy)
8. If explanted, give date (mm/dd/yyyy)
9. Device available for evaluation? (Do not send device to FDA)
   ☐ yes ☐ no ☐ returned to manufacturer on ____ (mm/dd/yyyy)

DSS
JUL 31 2001

10. Concomitant medical products and therapy dates (exclude treatment of event)

E. Reporter (see confidentiality section on back)

1. Name [redacted] phone # [redacted]

[redacted] Hospital; [redacted] Ave. [redacted]
Pharmacy
[redacted]
United States

2. Health professional? ☑ yes ☐ no
3. Occupation: Other Health Professional
4. Also reported to
   - ☐ manufacturer
   - ☐ user facility
   - ☐ distributor
5. If you do not want your identity disclosed to the manufacturer, place an "X" in this box. ☐

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Mail to: MEDWATCH, 5600 Fishers Lane, Rockville, MD 20852-9787 or FAX to: 1-800-FDA-0178

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Individual Safety Report

3767646-5-00-01

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

VOLUNTARY reporting
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nts and product problems

Internet Submission - Page 1 CUSR

Form Approved: OMB No. 0910-0291 Expires: 04/30/03
See OMB statement on reverse

FDA Use Only

Triage unit sequence # 148011

A. Patient information

1. **Patient identifier** [redacted] In confidence
2. **Age at time of event:** or **Date of birth:**
3. **Sex** ☐ female ☐ male
4. **Weight** ____ lbs or ____ kgs

B. Adverse event or product problem

1. ☑ **Adverse event** and/or ☐ **Product problem** (e.g., defects/malfunctions)

2. **Outcomes attributed to adverse event** (check all that apply)
- ☐ death ____ (mm/dd/yyyy)
- ☐ life-threatening
- ☑ hospitalization – initial or prolonged
- ☐ disability
- ☐ congenital anomaly
- ☐ required intervention to prevent permanent impairment/damage
- ☐ other: ____

3. **Date of event** (mm/dd/yyyy) 02/24/2001

4. **Date of this report** (mm/dd/yyyy) 07/28/2001

5. **Describe event or problem**

GI bleed orthostatic hypotension

6. **Relevant tests/laboratory data,** including dates

hgb= 6.2 hct= 20

7. **Other relevant history, including preexisting medical conditions** (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

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CTV148011

C. Suspect medication(s)

1. **Name** (Product Name) (Labeled Strength) (Mfr/Labeler)
- #1 excedrin
- #2

2. **Dose/Frequency/Route used**
- #1 prn
- #2

3. **Therapy dates** (if unknown, give duration) From To (or best estimate)
- #1 –
- #2 –

4. **Diagnosis for use** (separate indications with commas)
- #1
- #2

5. **Event abated after use stopped or dose reduced**
- #1 ☐ yes ☐ no ☑ doesn't apply
- #2 ☐ yes ☐ no ☐ doesn't apply

6. **Lot #** (if known)
- #1
- #2

7. **Exp. date** (if known)
- #1
- #2

8. **Event reappeared after reintroduction**
- #1 ☐ yes ☐ no ☐ doesn't apply
- #2 ☐ yes ☐ no ☐ doesn't apply

9. **NDC #** (for product problems only) – –

10. **Concomitant medical products** and therapy dates (exclude treatment of event)

D. Suspect medical device

1. **Brand name**

2. **Type of device**

3. **Manufacturer name & address**

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4. **Operator of device**
- ☐ health professional
- ☐ lay user/patient
- ☐ other: ____

6. model # MEDWATCH CTU
catalog # ____
serial # ____
lot # ____
other # ____

5. **Expiration date** (mm/dd/yyyy)

7. **If implanted, give date** (mm/dd/yyyy)

8. **If explanted, give date** (mm/dd/yyyy)

9. **Device available for evaluation?** (Do not send device to FDA) DSS
☐ yes ☐ no ☐ returned to manufacturer on ____ (mm/dd/yyyy)

10. **Concomitant medical products** and therapy dates (exclude treatment of event)

JUL 31 2001

E. Reporter (see confidentiality section on back)

1. **Name** **phone #** [redacted]

[redacted] Hospital; [redacted] Ave. [redacted]
Pharmacy
[redacted]
United States [redacted]

2. **Health professional?** ☑ yes ☐ no

3. **Occupation** Other Health Professional

4. **Also reported to**
- ☐ manufacturer
- ☐ user facility
- ☐ distributor

5. **If you do not want your identity disclosed to the manufacturer, place an "X" in this box.** ☐

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Individual Safety Report

3767656-8-00-01

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VOLUNTARY reporting by health professionals of adverse events and product problems

Internet Submission - Page 1

Form Approved: OMB No. 0910-0291 Expires: 04/30/03
See OMB statement on reverse

FDA Use Only

Triage unit sequence # 148016

A. Patient information

1. Patient identifier	2. Age at time of event: or Date of birth:	3. Sex	4. Weight
[redacted] In confidence		☑ female ☐ male	____ lbs or 64.1 kgs

B. Adverse event or product problem

1. ☑ **Adverse event** and/or ☐ **Product problem** (e.g., defects/malfunctions)

2. **Outcomes attributed to adverse event** (check all that apply)
- ☐ death ____ (mm/dd/yyyy)
- ☐ life-threatening
- ☑ hospitalization – initial or prolonged
- ☐ disability
- ☐ congenital anomaly
- ☐ required intervention to prevent permanent impairment/damage
- ☐ other: ____

3. **Date of event** (mm/dd/yyyy): 04/16/2001

4. **Date of this report** (mm/dd/yyyy): 07/29/2001

5. **Describe event or problem**

GI bleed 5-6 dark stools

6. **Relevant tests/laboratory data,** including dates

H/H 9.1/27 BRB in stools

7. **Other relevant history, including preexisting medical conditions** (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

artritis

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CTV148016 RECEIVED

C. Suspect medication(s)

1. Name (Product Name)	(Labeled Strength)	(Mfr/Labeler)
#1 asa	/ ASPIRIN	/
#2 vioxx	/	/

2. Dose/Frequency/Route used	3. Therapy dates (if unknown, give duration) From	To (or best estimate)
#1 81 mg / qd / Oral	#1	–
#2 50 mg / qd / Oral	#2	–

4. **Diagnosis for use** (separate indications with commas)
- #1 1995 had a head CT due to dizzines ?
- #2 osteoarthritis

5. **Event abated after use stopped or dose reduced**
- #1 ☐ yes ☐ no ☑ doesn't apply
- #2 ☐ yes ☐ no ☐ doesn't apply

6. **Lot #** (if known)
- #1
- #2

7. **Exp. date** (if known)
- #1
- #2

8. **Event reappeared after reintroduction**
- #1 ☐ yes ☐ no ☐ doesn't apply
- #2 ☐ yes ☐ no ☐ doesn't apply

9. **NDC #** (for product problems only)
- – –

10. **Concomitant medical products** and therapy dates (exclude treatment of event)

D. Suspect medical device

1. **Brand name**

2. **Type of device**

3. **Manufacturer name & address**

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4. **Operator of device**
- ☐ health professional
- ☐ lay user/patient
- ☐ other: ____

6. model # ____
catalog # MEDWATCH CTU
serial # ____
lot # ____
other # ____

5. **Expiration date** (mm/dd/yyyy)

7. **If implanted, give date** (mm/dd/yyyy)

8. **If explanted, give date** (mm/dd/yyyy)

9. **Device available for evaluation?** (Do not send device to FDA)
☐ yes ☐ no ☐ returned to manufacturer on DSS (mm/dd/yyyy)

10. **Concomitant medical products** and therapy dates (exclude treatment of event)

JUL 31 2001

E. Reporter (see confidentiality section on back)

1. **Name** [redacted] **phone #** [redacted]

[redacted] Hospital, [redacted] Ave. [redacted]
Pharmacy
[redacted]
United States

2. **Health professional?** ☑ yes ☐ no

3. **Occupation** Other Health Professional

4. **Also reported to**
- ☐ manufacturer
- ☐ user facility
- ☐ distributor

5. **If you do not want your identity disclosed to the manufacturer, place an "X" in this box.** ☐

FDA

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Individual Safety Report

3770218-X-00-01

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

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Internet Submission - Page 1

Form Approved: OMB No. 0910-0291 Expires: 04/30/03
See OMB statement on reverse

FDA Use Only
Triage unit sequence # 148300

A. Patient information

1. Patient identifier	2. Age at time of event: or Date of birth:	3. Sex	4. Weight
[redacted] In confidence		☐ female ☑ male	____ lbs or ____ kgs

B. Adverse event or product problem

1. ☑ Adverse event and/or ☐ Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)
- ☐ death ____ (mm/dd/yyyy)
- ☐ life-threatening
- ☑ hospitalization – initial or prolonged
- ☐ disability
- ☐ congenital anomaly
- ☐ required intervention to prevent permanent impairment/damage
- ☐ other: ____

3. Date of event (mm/dd/yyyy): 06/29/2001

4. Date of this report (mm/dd/yyyy): 08/01/2001

5. Describe event or problem

GI bleed, dizziness ibuprofen 6-8 tabs/ day asa 3/day

6. Relevant tests/laboratory data, including dates

EGD revealed shallow duodenal ulcer & erosis-no acute bleeding HgB=8.0 Hct=23

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

some ETOH use

MEDWATCH

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CT/148300 RECEIVED

C. Suspect medication(s)

1. Name (Product Name)	(Labeled Strength)	(Mfr/Labeler)
#1 ibuprofen	/	/
#2 asa	/	/

2. Dose/Frequency/Route used
- #1 / /
- #2 / /

3. Therapy dates (if unknown, give duration)
- #1 From ___ To (or best estimate) ___
- #2 ___ ___

4. Diagnosis for use (separate indications with commas)
- #1 chronic lower back pain
- #2

5. Event abated after use stopped or dose reduced
- #1 ☐ yes ☐ no ☑ doesn't apply
- #2 ☐ yes ☐ no ☐ doesn't apply

6. Lot # (if known)
- #1
- #2

7. Exp. date (if known)
- #1
- #2

8. Event reappeared after reintroduction
- #1 ☐ yes ☐ no ☐ doesn't apply
- #2 ☐ yes ☐ no ☐ doesn't apply

9. NDC # (for product problems only) – –

10. Concomitant medical products and therapy dates (exclude treatment of event)

DSS

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D. Suspect medical device

1. Brand name

2. Type of device

3. Manufacturer name & address

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AUG 0 3 2001

4. Operator of device
- ☐ health professional
- ☐ lay user/patient
- ☐ other: ____

5. Expiration date (mm/dd/yyyy)

6. model # MEDWATCH CTU
catalog # ____
serial # ____
lot # ____
other # ____

7. If implanted, give date (mm/dd/yyyy)

8. If explanted, give date (mm/dd/yyyy)

9. Device available for evaluation? (Do not send device to FDA)
☐ yes ☐ no ☐ returned to manufacturer on ____ (mm/dd/yyyy)

10. Concomitant medical products and therapy dates (exclude treatment of event)

E. Reporter (see confidentiality section on back)

1. Name [redacted] phone # [redacted]

[redacted] Hospital [redacted] Pharmacy; [redacted]
[redacted] Ave. [redacted]
[redacted] United States [redacted]

2. Health professional?	3. Occupation	4. Also reported to
☑ yes ☐ no	Other Health Professional	☐ manufacturer ☐ user facility ☐ distributor

5. If you do not want your identity disclosed to the manufacturer, place an "X" in this box. ☐

Mail to: MEDWATCH 5600 Fishers Lane Rockville, MD 20852-9787 or FAX to: 1-800-FDA-0178

FDA Form 3500

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

Individual Safety Report

3771396-9-00-01

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

VOLUNTARY reporting
ealth professionals of adverse vents and product problems
Internet Submission - Page 1

Form Approved: OMB No. 9910-0291 Expires: 04/30/03
See OMB statement on reverse

FDA Use Only

Triage unit sequence # 148440

A. Patient information

1. Patient identifier: 080601 (In confidence)
2. Age at time of event: 68 Years or Date of birth:
3. Sex: [ ] female [✓] male
4. Weight: ____ lbs or ____ kgs

B. Adverse event or product problem

1. [✓] Adverse event and/or [ ] Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)
- [ ] death (mm/dd/yyyy)
- [✓] life-threatening
- [✓] hospitalization - initial or prolonged
- [ ] disability
- [ ] congenital anomaly
- [ ] required intervention to prevent permanent impairment/damage
- [ ] other

3. Date of event (mm/dd/yyyy): 07/13/2001

4. Date of this report (mm/dd/yyyy): 08/06/2001

5. Describe event or problem:

Patient underwent a cardiac angioplasty with stent placement on at a local hospital within the previous week. He was doing well initially, however, during his daily walk today, he felt very weak and had difficutly getting home. He felt light-headed & dizzy. He was brought into the Emergency room where he was found to have a blood pressure of 122/41 and pulse of 56. He was also noted to have melanotic stools. The patient was admitted for further evaluation of his apparent GI bleeding and anemia.

6. Relevant tests/laboratory data, including dates:

Hgb - 4.5 -7/13/01-

DSS

AUG 07 2001

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.):

NIID, hypertension, chronic back pain, history of orthopedic surgeries on both ankles.

MEDWATCH

AUG 07 2001

C. Suspect medication(s)

1. Name (Product Name) / (Labeled Strength) / (Mfr/Labeler)
- #1 Plavix / 75 mg /
- #2 Aspirin / 325 mg /

2. Dose/Frequency/Route used
- #1 75 mg / daily / Oral
- #2 325 mg / daily / Oral

3. Therapy dates (if unknown, give duration) From / To (or best estimate)
- #1 07/06/2001 - 07/13/2001
- #2 07/06/2001 - 07/13/2001

4. Diagnosis for use (separate indications with commas)
- #1 status post cardiac stent placement
- #2 coronary artery disease

5. Event abated after use stopped or dose reduced
- #1 [ ] yes [ ] no [✓] doesn't apply
- #2 [ ] yes [ ] no [✓] doesn't apply

6. Lot # (if known)
- #1
- #2

7. Exp date (if known)
- #1
- #2

8. Event reappeared after reintroduction
- #1 [ ] yes [ ] no [✓] doesn't apply
- #2 [ ] yes [ ] no [✓] doesn't apply

9. NDC # (for product problems only)
- -
- -

10. Concomitant medical products and therapy dates (exclude treatment of event)

Tiazac 240 mg qd, Claritin 10 mg qd
Precose 100 mg TID, Atenolol 100 mg QD,
Diovan 80 mg qd, Actose 20mg QD,
Ranitidine 150m

D. Suspect medical device

1. Brand name

2. Type of device

3. Manufacturer name & address

4. Operator of device
- [ ] health professional
- [ ] lay user/patient
- [ ] other:

5. Expiration date (mm/dd/yyyy)

6.
- model # RECEIVED
- catalog # AUG 07 2001
- serial #
- lot # MEDWATCH CTU
- other #

7. If implanted, give date (mm/dd/yyyy)

8. If explanted, give date (mm/dd/yyyy)

9. Device available for evaluation? (Do not send device to FDA)
- [ ] yes [ ] no [ ] returned to manufacturer on ____ (mm/dd/yyyy)

10. Concomitant medical products and therapy dates (exclude treatment of event)

E. Reporter (see confidentiality section on back)

1. Name: [redacted] PharmD
[redacted] Health System Pharmacy [redacted]
[redacted] United States [redacted]

phone # [redacted]

2. Health professional?
- [✓] yes [ ] no

3. Occupation: Pharmacist

4. Also reported to
- [ ] manufacturer
- [✓] user facility
- [ ] distributor

5. If you do not want your identity disclosed to the manufacturer, place an "X" in this box [✓]

FDA

Mail to: MEDWATCH, 5600 Fishers Lane, Rockville, MD 20852-9787

or FAX to: 1-800-FDA-0178

RECEIVED

FDA Form 3500

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

CTU 148440

Individual Safety Report

3771396-9-00-02

148446

MEDWATCH

For VOLUNTARY reporting by health professionals of adverse events and product problems
Internet Submission - Page 5

C10. Concomitant medical products and therapy dates continued

g BID, Lasix 40mg QD, Glyburide 5 mg BID

D10. Concomitant medical products and therapy dates continued

DSS

AUG 07 2001

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Rockville, MD 20852-9787

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